Chapter 37. Medication Administration Safety

Ronda G. Hughes, Mary A. Blegen

Background

The Institute of Medicine's (IOM) first Quality Chasm report, *To Err Is Human: Building a Safer Health System*,[1] stated that medication-related errors (a subset of medical error) were a significant cause of morbidity and mortality; they accounted "for one out of every 131 outpatient deaths, and one out of 854 inpatient deaths"[1] (p. 27). Medication errors were estimated to account for more than 7,000 deaths annually.[1] Building on this work and previous IOM reports, the IOM put forth a report in 2007 on medication safety, *Preventing Medication Errors*.[2] This report emphasized the importance of severely reducing medication errors, improving communication with patients, continually monitoring for errors, providing clinicians with decision-support and information tools, and improving and standardizing medication labeling and drug-related information.

With the growing reliance on medication therapy as the primary intervention for most illnesses, patients receiving medication interventions are exposed to potential harm as well as benefits. Benefits are effective management of the illness/disease, slowed progression of the disease, and improved patient outcomes with few if any errors. Harm from medications can arise from unintended consequences as well as medication error (wrong medication, wrong time, wrong dose, etc.). With inadequate nursing education about patient safety and quality, excessive workloads, staffing inadequacies, fatigue, illegible provider handwriting, flawed dispensing systems, and problems with the labeling of drugs, nurses are continually challenged to ensure that their patients receive the right medication at the right time. The purpose of this chapter is to review the research regarding medication safety in relation to nursing care. We will show that while we have an adequate and consistent knowledge base of medication error reporting and distribution across phases of the medication process, the knowledge base to inform interventions is very weak.

Defining Medication Errors

Shared definitions of several key terms are important to understanding this chapter. Drugs are defined as "a substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease; a substance (other than food) intended to affect the structure or any function of the body; and a substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device."[3] Medications include, but are not limited to, any product considered a drug by the Food and Drug Administration (FDA).[3] Given the number and variety of definitions for medication errors, the IOM has recommended that international definitions be adopted for medication error, adverse drug events, and near misses.[2]

Medication Errors

One commonly used definition for a medication error is:

> Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.[4]

Some of the factors associated with medication errors include the following:

- Medications with similar names or similar packaging
- Medications that are not commonly used or prescribed
- Commonly used medications to which many patients are allergic (e.g., antibiotics, opiates, and nonsteroidal anti-inflammatory drugs)
- Medications that require testing to ensure proper (i.e., nontoxic) therapeutic levels are maintained (e.g., lithium, warfarin, theophylline, and digoxin)

Look-alike/sound-alike medication names can result in medication errors. Misreading medication names that look similar is a common mistake. These look-alike medication names may also sound alike and can lead to errors associated with verbal prescriptions. The Joint Commission publishes a list of look-alike/sound-alike drugs that are considered the most problematic medication names across settings. (This list is available at www.jointcommission.org/NR/rdonlyres/C92AAB3F-A9BD-431C-8628-11DD2D1D53CC/0/lasa.pdf.)

Medication errors occur in all settings[5] and may or may not cause an adverse drug event (ADE). Medications with complex dosing regimens and those given in specialty areas (e.g., intensive care units, emergency departments, and diagnostic and interventional areas) are associated with increased risk of ADEs.[6] Phillips and colleagues[7] found that deaths (the most severe ADE) associated with medication errors involved central nervous system agents, antineoplastics, and cardiovascular drugs. Most of the common types of errors resulting in patient death involved the wrong dose (40.9 percent), the wrong drug (16 percent), and the wrong route of administration (9.5 percent). The causes of these deaths were categorized as oral and written miscommunication, name confusion (e.g., names that look or sound alike), similar or misleading container labeling, performance or knowledge deficits, and inappropriate packaging or device design.

Adverse Drug Events and Adverse Drug Reactions

Adverse drug events are defined as injuries that result from medication use, although the causality of this relationship may not be proven.[8] Some ADEs are caused by preventable errors. ADEs that are not preventable are often the result of adverse drug reactions (ADRs), which are defined as "any response to a drug which is noxious and unintended and which occurs at doses normally used for prophylaxis, diagnosis or therapy of disease, or the modification of physiological function, given that this noxious response is not due to medication error."[9] Potential ADEs or near misses/close calls are medication errors that do not cause any harm to the patient because they are intercepted before they reach the patient or because the patient is able to physiologically absorb the error without any harm.

An adverse drug reaction is defined as "an undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both."[10] ADRs can be manifested as diarrhea or constipation, rash, headache, or other nonspecific symptoms. One of the challenges presented by ADRs is that prescribers may attribute the adverse effects to the patient's underlying condition and fail to recognize the patient's age or number of medications as a contributing factor.[11] According to Bates and colleagues,[12] more attention needs to be directed to ADEs—including both ADRs and preventable ADEs—which range in severity from insignificant to fatal.

Black Box Warnings and High-Alert Medications

In 1995, the FDA established the black box warning (BBW) system to alert prescribers to drugs with increased risks for patients. These warnings are intended to be the strongest labeling requirement for drugs or drug products that can have serious adverse reactions or potential safety hazards, especially those that may result in death or serious injury.[13] While the FDA does not issue a comprehensive list of drugs with BBWs,[14] some of the BBW drugs are celecoxib (Celebrex), warfarin, rosiglitazone (Avandia), methylphenidate (Ritalin), estrogen-containing contraceptives, and most antidepressants.[15] One study funded by the Agency for Healthcare Research and Quality found 40 percent of patients were taking a medication with a BBW and that many of those patients did not receive the recommended laboratory monitoring. The authors concluded that BBWs did not prevent the inappropriate use of high-risk medications.[16]

Medication errors can be considered a sentinel event when they are associated with high-alert medications. According to the Institute for Safe Medication Practices (ISMP), "High-alert medications are those likely to cause significant harm when used in error." The top five high-alert medications are "insulin, opiates and narcotics, injectable potassium chloride (or phosphate) concentrate, intravenous anticoagulants (heparin), and sodium chloride solutions above 0.9 percent"[17] (p. 339). ISMP's list of high-alert medications is available at: www.ismp.org/tools/highalertmedications.pdf.

The Prevalence and Impact of Medication Errors

In the Harvard Medical Practice Study, Leape and colleagues[18, 19] examined more than 30,000 hospital discharges selected at random from 51 hospitals in the State of New York in 1984. The researchers found that 3.7 percent of hospitalizations involved adverse events that prolonged hospital stay or were manifested as a new disability at the time of discharge. About one in four of these adverse events were judged to be attributable to negligence, and 58 percent were judged to be preventable.

It is difficult to reduce or eliminate medication errors when information on their prevalence is absent, inaccurate, or contradictory. Bates[20] put forth the notion that for every medication error that harms a patient, there are 100, mostly undetected, errors that do not. Most medication errors cause no patient harm or remain undetected by the clinician.[20, 21] The low rate of detected errors makes assessing the effectiveness of strategies to prevent medication errors challenging.

Rates of medication errors vary, depending on the detection method used. For example, among hospitalized patients, studies have shown that errors may be occurring as frequently as one per patient per day.[5, 22] In pediatric intensive care unit (ICU) studies, reported medication error rates have ranged from 5.7[23] and 14.6 per 100 orders[24] to as high as 26 per 100 orders.[25]

The impact of medication errors on morbidity and mortality were assessed in a case-control analysis of ADEs in hospitalized patients during a 3-year period.[26] The investigators found significant increases in (a) the cost of hospitalization from increased length of stay, ranging from $677 to $9,022; (b) patient mortality (odds ratio = 1.88 with a 95% confidence interval); and (c) postdischarge disability. The impact was less in male patients, younger patients, and patients with less severe illnesses and in certain diagnosis-related groups.

Without an infrastructure to capture and assess all medication errors and near misses, the real number is not known. These rates could be expected to be higher once patient safety organizations begin to collect nationwide errors and health care clinicians become more comfortable and skilled in recognizing and reporting all medication errors. The concern raised in *To Err Is Human*[1] about the potential prevalence and impact of ADEs—2 out of every 100 hospitalized patients—was just the beginning of our understanding of the potential magnitude of the rates of medication errors. The concern continues, as is seen in the most recent IOM report, *Preventing Medication Errors*,[2] which states that "a hospital patient is subject to at least one medication error per day, with considerable variation in error rates across facilities" (pp. 1–2). Yet, despite numerous research findings, we cannot estimate the actual rates because they vary by site, organization, and clinician; because not all medication errors are detected; and because not all detected errors are reported.

Error-Prone Processes

There are five stages of the medication process: (a) ordering/prescribing, (b) transcribing and verifying, (c) dispensing and delivering, (d) administering, and (e) monitoring and reporting.[2] Monitoring and reporting is a newly identified stage about which there is little research. Some of the most noted and early work on medication safety found hospitalized patients suffer preventable injury or even death as a result of ADEs associated with errors made during the prescribing, dispensing, and administering of medications to patients,[12, 27–29] although the rates of error in the stages of the medication process vary. A few studies have indicated that one of every three medication errors could be attributed to either a lack of knowledge about the medication or a lack of knowledge about the patient.[30]

Prescribing/ordering. Of the five stages, ordering/prescribing most often initiates a series of errors resulting in a patient receiving the wrong dose or wrong medication. In this stage, the wrong drug, dose, or route can be ordered, as can drugs to which the patient has known allergies. Workload, knowledge about the prescribed drug, and attitude of the prescriber—especially if there is a low perceived importance of prescribing compared with other responsibilities—are significantly associated with ADEs.[31, 32] Furthermore, if nurses or pharmacists question a prescriber about an order, they can be confronted with aggressive behavior, which may inhibit future questioning and seeking clarification.[33] The proportion of medication errors attributable to the ordering/prescribing stage range from 79 percent[29] to 3 percent.[34] Examples of the types of errors committed in this stage include illegible and/or incomplete orders, orders for contraindicated medications, and inappropriate doses. Similar results have been found in mandatory adverse event reporting systems. An analysis of 108 reports associated with significant harm or death reported to the State of New York noted that, when the error occurred during the prescribing stage, written prescriptions accounted for 74 percent of the errors, and verbal orders accounted for 15 percent.[6]

While the preponderance of the research focuses on physician prescribing, there is a brief discussion about the role of advanced practice nurses in prescribing to ensure safety. One

investigation of the occurrence of ADRs in outpatient veterans found no difference in ADR events between physicians and nurse practitioners.[11] Prescribers may make changes in medication therapy (e.g., change the dosage or discontinue the medication) in response to ADRs (e.g., constipation, rash) or other indications communicated to them by nurses or patients.

Transcribing, dispensing, and delivering. In some settings, medication orders are transcribed, dispensed, and then delivered for nurse administration. In certain circumstances and settings, both nurses and pharmacists are involved in transcribing, verifying, dispensing, and delivering medications. Yet errors of these two stages (transcribing and verifying, dispensing and delivering) have been predominately studied for pharmacists. Pharmacists can have an important role in intercepting and preventing prescribing/ordering errors.[35] One study found that while dispensing errors were 14 percent of the total ADEs, pharmacists intercepted 70 percent of all physician ordering errors.[27] Pharmacy dispensing errors have been found to range from 4 percent to 42 percent of errors.[36] Examples of errors that can be initiated at the transcribing, dispensing, and delivering stages include failure to transcribe the order, incorrectly filling the order, and failure to deliver the correct medication for the correct patient.

Medication administration. Nurses are primarily involved in the administration of medications across settings. Nurses can also be involved in both the dispensing and preparation of medications (in a similar role to pharmacists), such as crushing pills and drawing up a measured amount for injections. Early research on medication administration errors (MAEs) reported an error rate of 60 percent,[34] mainly in the form of wrong time, wrong rate, or wrong dose. In other studies, approximately one out of every three ADEs were attributable to nurses administering medications to patients.[21, 28] In a study of deaths caused by medication errors reported to the FDA from 1993 to 1998, injectable drugs were most often the problem;[7] the most common type of error was a drug overdose, and the second most common type of error was administering the wrong drug to a patient. The 583 causes of the 469 deaths were categorized as miscommunication, name confusion, similar or misleading labeling, human factors (e.g., knowledge or performance deficits), and inappropriate packaging or device design. The most common causes were human factors (65.2 percent), followed by miscommunication (15.8 percent).

Nurses are not the only ones to administer medications. Physicians, certified medication technicians, and patients and family members also administer medications. Part of the challenge in understanding the impact of nursing in medication administration is the need for research that clearly differentiates the administrators of medications. Several studies have reported medication administration errors that have included nonnurses.[37, 38] Among many reasons for the prevalence of nurse involvement in medication errors is that nurses may spend as much as 40 percent of their time in medication administration.[39]

A large-scale study by the U.S. National Council of State Boards of Nursing assessed whether there were any identifiable characteristics common to those nurses who committed medication administration errors. The most significant finding was that "the age, educational preparation and employment setting of RNs disciplined for medication administration errors are similar to those of the entire RN population"[40] (p. 12).

The "rights" of medication administration include right patient, right drug, right time, right route, and right dose. These rights are critical for nurses. A survey of patients discharged from the hospital found that about 20 percent were concerned about an error with their medications, and 15 percent of them were concerned about being harmed from mistakes by nurses compared to 10 percent who were concerned about mistakes by physicians.[41] However, the complexity of

the medication process has led to the formulation of the rights of nurses in the area of medication administration. The essential environmental conditions conducive to safe medication practices include (a) the right to complete and clearly written orders that clearly specify the drug, dose, route, and frequency; (b) the right to have the correct drug route and dose dispensed from pharmacies; (c) the right to have access to drug information; (d) the right to have policies on safe medication administration; (e) the right to administer medications safely and to identify problems in the system; and (f) the right to stop, think, and be vigilant when administering medications.[42]

Types of Medication Errors

Leape and colleagues[27] reported more than 15 types of medication errors: wrong dose, wrong choice, wrong drug, known allergy, missed dose, wrong time, wrong frequency, wrong technique, drug-drug interaction, wrong route, extra dose, failure to act on test, equipment failure, inadequate monitoring, preparation error, and other. Of the 130 errors for physicians, the majority were wrong dose, wrong choice of drug, and known allergy. Among the 126 nursing administration errors, the majority were associated with wrong dose, wrong technique, and wrong drug. Each type of error was found to occur at various stages, though some more often during the ordering and administration stages.

Since the study by Leape and colleagues, research has captured some of the types of error identified by Leape and added yet others (e.g., omission due to late transcription,[43] wrong administration technique,[24, 44, 45] and infiltration/extravasation.[46] Reporting incidences by type of error, rather than the stage it was associated with, leads to equivocal implications for nursing practice. The categorization approach used determines whether the implication can be targeted to stage, and therefore discipline, or to types of error. For example, 11 studies reported rates of types of medication errors using institution-specific and national databases, yet not specifying whether the error occurred during the prescribing, dispensing, or administration stage of the medication process or not clearly specifying administration errors associated with nurse administration. One of these studies analyzed deaths associated with medication errors, finding that the majority of deaths were related to overdose and wrong drug[7]—again, not specified by stage. Yet among these, it may be possible to see that wrong dose, dose omission, wrong drug, and wrong time are the most frequent type of medication error. Even then, comparisons and practice implications are challenging due to the lack of standardization among the types of categories used in research.

Working Conditions Can Facilitate Medication Errors

Following the release of *To Err Is Human*,[1] the focus on deaths caused by medication errors targeted system issues, such as high noise levels and excessive workloads,[47] and system interventions, such as the need for computerized order entry, unit dose (e.g., single-dose packaging), and 24-hour pharmacy coverage.[48] The IOM's report, *Crossing the Quality Chasm*,[49] put forth the concept that poor designs set the workforce up to fail, regardless of how hard they try. Thus, if health care institutions want to ensure safer, higher-quality care, they will need to, among other things, redesign systems of care using information technology to support clinical and administrative processes.

We are at the beginning stage of assessing and understanding the potential association between working conditions/environment and medication errors. Early research in this area found a relationship between characteristics of the work environment for nurses and medication

errors.[30, 50, 51] For example, Leape and colleagues[27] found an association between the occurrence of medication errors and the inability to access information and failure to follow policies and guidelines. Also, research has found that health care clinicians should be aware of the repeated patterns of medication errors and near misses to provide insight on how to avoid future errors.[52]

The system approach to safety emphasizes the human condition of fallibility and anticipates that errors will occur, even in the best organizations with the best people working in them. This approach focuses on identifying predisposing factors within the working environment or systems that lead to errors.[53] Reason's[53] model of accident causation describes three conditions that predicate an error:

1. *Latent conditions*—Organizational processes, management decisions, and elements in the system, such as staffing shortages, turnover, and medication administration protocols.
2. *Error-producing conditions*—Environmental, team, individual, or task factors that affect performance, such as distractions and interruptions (e.g., delivering and receiving food trays), transporting patients, and performing ancillary services (e.g., delivery of medical supplies, blood products).[49]
3. *Active failures*—errors involving slips (actions in which there are recognition or selection failures), lapses (failure of memory or attention), and mistakes (incorrect choice of objective, or choice of an incorrect path to achieve it), compared to violation, where rules of correct behavior are consciously ignored.

Threats to medication safety include miscommunication among health care providers, drug information that is not accessible or up to date, confusing directions, poor technique, inadequate patient information, lack of drug knowledge, incomplete patient medication history, lack of redundant safety checks, lack of evidence-based protocols, and staff assuming roles for which they are not prepared. An additional risk is a hospital without 24-hour pharmacy coverage, especially when procedural barriers to offset the risk of accessing high-risk drugs are absent.[6]

Recognizing and Reporting Medication Administration Errors

Error reporting strategies are critical to the implementation of effective system-level approaches to reduce medication errors and ADEs.[54] However, the usefulness of many reporting strategies depends directly on the level of response.[55] To be effective, medication error reporting needs to be ongoing and part of a continuous quality improvement process.[56, 57]

Previous research has found that when nurses voluntarily report medication administration errors, as few as 10 to 25 percent of errors are reported.[28] As discussed in the chapter on error reporting, there were numerous surveys of hospital nurses' perceptions of what constitutes an MAE, why these types of errors occur,[58–61] and what the barriers to reporting are.[58–72] The three most significant barriers to reporting were (a) a hierarchical hospital culture/structure where the nursing staff disagreed about the definition of reportable errors, (b) fear of the response and reaction of hospital management/administrators and peers to a reported error, and (c) the amount of time and effort involved in documenting and reporting an error. Together these studies indicate that the medication errors that are reported do not represent the actual incidence of medication errors.

Without reporting, many errors may not be known. Based on a survey of nurses on barriers to reporting, Wakefield and colleagues[62] suggested several strategies to increase the reporting of MAEs: agreement on the definition of error; supporting and simplifying reporting of errors; institutionalizing a culture that rewards and learns from error reporting (i.e., a culture of safety, where learning is encouraged and blaming discouraged); capitalizing on feedback reports to

determine system factors contributing to error; and ensuring positive incentives for MAE reporting.

Incident reports, retrospective chart reviews, and direct observation are methods that have been used to detect errors. Incident reports, which capture information on recognized errors, can vary by type of unit and management activities;[73] they represent only a few of the actual medication errors, particularly when compared to a patient record review.[74] Chart reviews have been found to be most useful in detecting errors in ordering/prescribing, but not administration.[75, 76] Direct observation of administration with comparison to the medication administration record detects most administration errors; however, it cannot detect ordering errors and, in some systems, transcribing and dispensing errors. There were two studies that compared detection methods. One of these studies of medication administration in 36 hospitals and skilled nursing facilities found 373 errors made on 2,556 doses.[77] The comparison of three detection methods found that chart review detected 7 percent of the observed errors, and incident reports detected only 1 percent. Direct observation was able to detect 80 percent of true administration errors, far more than detected through other means. A second study compared detection methods and found that more administration errors were detected by observation (a 31.1 percent error rate) than were documented in the patients' medical records (a 23.5 percent error rate).[78] Therefore, no one method will do it all. When automated systems that use triggers are not in place, multiple approaches such as incident reports, observation, patient record reviews, and surveillance by pharmacist may be more successful.[79]

The wide variation in reported prevalence and etiology of medication errors is in part attributable to the lack of a national reporting system or systems that collect both errors and near misses. State-based and nationally focused efforts to better determine the incidence of medication errors are also available and expanding (Patient Safety and Quality Improvement Act of 2005). The FDA's Adverse Event Reporting System (AERS), which is part of the FDAs' MedWatch program (www.fda.gov/medwatch), U.S. Pharmacopeia's (USP's) MEDMARX® database (www.medmarx.com), and the USP's Medication Errors Reporting Program (MERP; www.ismp.org/orderforms/reporterrortoISMP.asp), in cooperation with the ISMP, collect voluntary reports on actual and potential medication errors, analyze the information, and publish information on their findings.

Research reported to date clearly reveals that medication errors are a major threat to patient safety, and that these errors can be attributed to all involved disciplines and to all stages of the medication process. Unfortunately, the research also reveals that we have only weak knowledge of the actual incidence of errors. Our information about ADEs (those detected, reported, and treated) is better, but far from complete. With this knowledge of the strengths and limitations of the research, this chapter will consider the evidence regarding nurses' medication administration.

Research Evidence—Medication Administration by Nurses

The research review targeted studies involving medication administration by nurses. This excluded several studies that assessed medication administration errors without differentiating whether the errors were associated with physicians, assistants, or nurses. None of these studies included interventions.

Rates and Types of Medication Administration Errors

Thirteen studies explicitly reported types of MAEs associated with nurses. The incidence of MAEs was detected either formally through incident reports, chart reviews, or direct observation, or informally through anonymous surveys. Two studies conducted retrospective assessments, one using medical records[43] and the other malpractice claims.[80] Seven studies assessed self-reported MAEs from a nationally representative database[44, 81–83] or self-reported errors using a nationally representative sample.[84–86] None of these self-reported MAEs were verified. Eight studies assessed MAEs using direct observation of the medication administration process.[24, 37, 78, 87–91]

The incidence of MAEs varied widely with the different research designs and samples. Using chart reviews, Grasso and colleagues[43] found that 4.7 percent of doses were administered incorrectly. Direct observation studies placed the estimate of total incorrect doses between 19 percent and 27 percent,[87] and when an extra review was done to separate the errors into stages of the medication process, between 6 percent and 8 percent of doses were in error because of administration. The majority of types of MAEs reported were wrong dose, wrong rate, wrong time, and omission. All of the studies reviewed here reported wrong drug and dose, but varied across the other types of MAE categories (see Evidence Table 1); this was dependent upon the study methodology.

Five studies evaluated self-reported MAEs, involving incident reports and informal reports.[38, 44, 81, 82] The most common types of reported errors were wrong dose, omission, and wrong time. Four of these studies[38, 81–83] assessed a large secondary, nationally representative database containing MAEs reported to the MEDMARX database over five years.[38, 81, 82, 44] found in the error reports submitted by nursing students that the majority of MAEs were associated with omission, wrong dose, wrong time, and extra dose. Of the reported contributing factors, 78 percent were due to the inexperience of the nurse. The Beyea and Hicks[81, 82] studies looked at errors associated with the operating room, same-day surgery, and postanesthesia; they found the majority of errors attributable to administration but did not classify them by error type. The other study reviewed 88 incident reports from a long-term care facility submitted during a 21-month period. It found that the majority of MAEs were associated with errors involving interpreting or updating the medication administration record, delayed dose, wrong dose, or wrong drug.[92] A separate component of this study surveyed administrative and clinical nurses and found that they believed the majority of medication errors occurred at either the administration or dispensing stage.

Two other studies assessed the type of MAEs reported by nurses in nationwide surveys.[84, 85] While the majority (57 percent) of errors reported by critical care nurses involved MAEs, an additional 28 percent of reported errors involved near misses. Medication administration errors involving wrong time, omission, and wrong dose accounted for 77.3 percent of errors, while wrong drug and wrong patient accounted for 77.8 percent of near misses. The most frequent types of medication errors were wrong time (33.6 percent), wrong dose (24.1 percent), and wrong drug (17.2 percent), and the three most frequent types of near misses were wrong drug (29.3 percent), wrong dose (21.6 percent), and wrong patient (19.0 percent).[85] Many of the reported MAEs in ICUs involved intravenous medications and fluids.[84] In these surveys, the nurses who reported making errors described between two and five errors during a 14-day period.

At the more advanced stage of incident reports, one study reviewed 68 malpractice cases involving MAEs in Sweden.[80] Among the cases reviewed, the majority of MAEs made by nurses

involved wrong dose. When the nurses delegated the drug administration to subordinate staff, the majority of MAEs involved wrong drug or wrong concentration of a drug. Errors, which were reported to the immediate supervisor, were also reported to the physician in 65 percent of cases. The reported causes of MAEs were lack of administration protocols, failure to check orders, ineffective nurse supervision when delegating administration, and inadequate documentation.

One study assessed medication errors using 31 medical records of patients discharged from a psychiatric hospital and found a total of 2,194 errors.[43] Of these, 997 were classified as MAEs (4.7 percent of all doses, and 66 percent of all errors). Of these, 61.9 percent were due to scheduled doses not documented as administered, 29.1 percent as drugs administered without an order, 8 percent as missed doses because of late transcription, and 3 percent resulting from orders not being correctly entered in the pharmacy computer.

Table 1. Comparison of the Incidence of Medication Administration Errors by Type Categories

	Buckley 2007[24] n = 15	Tang 2007[93] n = 72	Balas 2006[84] n = 127	Kopp 2006[45] n = 132	Wolf 2006[44] n = 1,305	Prot 2005[78] n = 538	Handler 2004[92] n = 88	Colen 2003[88] n = 1,077	Tissot 2003[91] n = 78	Flynn 2002[77] n = 457	Kapborg 1999[80] n = 37
	Percentages (%)										
Wrong patient	-	-	4.7	-	9.2	-	4.5	0		-	16.2
Wrong drug/unauthorized drug	0	26.4	10.2	0	8.4	12	11.3	0.46	13	3.7	13.5
Wrong dose	26.7	36.1	20.5	12	17.2	15	19.3	1.0	12	18.4	51.4
Wrong route	0	8.3	3.9	0	3.6	19	-	0.19		1.3	-
Wrong time/frequency	26.7	18.1	37.8	10	16.9	36	29.5	20.0	26	42.9	-
Wrong form	0	-	-	0	0.4	8	-	0.09		3.9	-
Wrong administration technique	20	-	-	14	3.4	3	-	0.19	4	0.4	-
Omission	0	-	22.0	48	19.0	5	-	3.3	16	27.6	2.7
Extra dose	26.7	-	-	14	14.1	0	-	-	-	1.8	-
Deteriorated drug	-	-	-	-	-	2	-	-	-	-	-
Drug past expiration date	-	-	-	-	-	-	-	-	-	-	5.4
Drug reaction/allergy	0	-	-	0	-	-	-	-	-	-	-
Infiltration/extravasation	-	-	-	-	-	-	-	-	-	-	-
Maintenance intravenous fluid/total parenteral nutrition	0	-	-	2	-		-	-	-	-	-
Wrong concentration	-	-	-	-	-	-	-	-	-	-	8.1
Wrong drug preparation	-	-	-	-	3.1	-	-	0.09	4	-	-
Wrong rate	-	-	-	-	-	-	-	-	19	-	-

Wrong solution	-	-	-	-	-	-	-	0	-	-	-
Wrong storage	-	-	-	-	-	-	-	-	-	-	2.7
Other/Not specified	-	-	0.8	-	-	-	35.2	1.5	6	-	-

Note: "-" represents variable not included in analysis or not reported.

The number of studies using direct observation of medication administration is increasing in response to the concern about the accuracy of other sources of data. Ten studies were found, only three of which were done in the United States. While we attempt to summarize across these studies, it is difficult to determine consistency across studies as each focused on different sets of errors (some only intravenous errors, some included gastrointestinal tube technique) and were conducted in different settings. In many of the non-U.S. studies, nurses dispensed drugs from ward stock and prepared many of the intravenous solutions for administration.

Three observational studies were conducted in pediatric units—one in France,[78] one in Switzerland,[25] and one in the United States.[24] Buckley[24] reported 52 of the 263 doses (19 percent) observed to be in error, but only 15 (6 percent) of those were in the administration stage. Those 15 were nearly evenly divided among wrong dose, wrong time, wrong technique, and extra dose categories. Prot[78] reported nearly 50 percent more MAEs. Of the 1,719 observed doses, 467 (27 percent) were in error, including wrong time; excluding wrong-time errors, the error rate was 13 percent of doses. The categories with the most MAEs in Prot's study were wrong time, wrong route (GI tube versus oral), wrong dose, unordered drug, wrong form, and omissions. Schneider and colleagues[25] reported an overall 26.9 percent error rate with wrong-time errors, and an 18.2 percent rate excluding wrong-time errors. Common errors in addition to wrong time were wrong dose preparation and wrong administration technique.

The incidence of intravenous drug errors was observed in three studies, one in England,[89] one in Germany,[90] and one in both countries.[37] About 50 percent of the doses were determined to contain at least one error. Compared to other studies, this rate is surprisingly high, and it included preparation technique errors (selection of diluent/solvent) as well as administration errors (rate of bolus injection and infusion rate). Part of the explanation may come from institutional (type of pharmacy support available) and professional training factors. (German nurses are not trained to do intravenous medications.)

Three studies focused on medication administration in ICUs in the United States,[45] in France,[91] and in the Netherlands.[94] Kopp and colleagues[45] looked at all medication errors and report that 27 percent of doses were in error; of these 32 percent could be attributed to the administration stage. Within the MAEs, most were omitted medications; the rest were evenly distributed among wrong dose, extra dose, and wrong technique. Few wrong-time errors were noted. Tissot[91] and van den Bernt[94] examined only administration stage errors and reported very different rates. Tissot reported 6.6 percent of the 2,009 observed doses were in error, most from wrong dose, wrong rate, and wrong preparation technique. Excluding wrong-time errors, van den Bernt reported a 33 percent error rate that included preparation errors with diluent/solvent issues, infusion-rate errors, and chemical incompatibility of intravenous drugs. It is likely that the differences in rates across these studies are due to the range of error types observed in each study as well as the varying responsibilities of nurses in the three countries.

The most extensive observation study, by Barker and colleagues,[87] conducted observations of medication administration in 36 randomly selected health care facilities (acute and long-term care) in two States in the United States. Of the 3,216 doses observed, 605 (19 percent) contained at least one error. Nearly half of those errors were wrong-time errors. Other common types of errors included omission, wrong dose, and unauthorized (unordered) drug. In a much smaller study conducted in the Netherlands, Colen, Neef, and Schuring[88] found an MAE rate of 27 percent, with most of these wrong-time errors. The rate of MAEs without wrong time was approximately 7 percent, and most of those were omissions.

Information from these research studies forms a consistent picture of the most common types of MAEs. These are wrong time, omissions, and wrong dose (including extra dose). Rates of error derived from direct observation studies ranged narrowly between 20 and 27 percent including wrong-time errors, and between 6 and 18 percent excluding wrong-time errors. The alarming exception to this was the nearly 50 percent error rate in observation of intravenous medication in ICUs in Europe.

Evidence Table 1. Types of Reported and Observed Medication Administration Errors (MAEs)

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Balas 2004[85]	Type of MAEs	Cross-sectional study	Voluntary, self-reported recording of 14 days of shift work, sleep, and errors using a journal	393 full-time registered nurses (RNs) in hospitals responded to the survey.	37.8% of nurses reported medication errors and near errors; made on average between 2 and 5 errors. Reported top types of medication errors were wrong time (33.6%), wrong dose (24.1%), and wrong drug (17.2%), compared to the top three types of near errors, which were wrong drug (29.3%), wrong dose (21.6%), and wrong patient (19.0%).
Balas 2006[84]	Types of MAEs or near errors	Cross-sectional study	Voluntary, self-reported recording of 14 days of shift work, sleep, and errors using a journal	502 RNs in critical care units throughout the United States	Of the 224 errors and 350 near errors, 56.7% involved medications. Wrong time, omission, and wrong dose accounted for 77.3% of MAEs, and wrong dose, wrong drug, and wrong patient accounted for 77.8% of near misses.
Barker 2002[87]	Types of MAEs	Cross-sectional	Observation of 3,216 doses administered by nurses in 36 randomly selected institutions	12 accredited hospitals, 12 nonaccredited hospitals, and 12 nursing homes	19% of doses were in error including wrong time, 11% excluding wrong time. The most frequent errors besides wrong time were omissions and wrong dose in all three types of institutions.
Buckley 2007[24]	Types of MAEs	Prospective cohort study	Direct observation over 6 months of medication process, determining actual and potential errors. Observers would intervene if error was considered harmful to patient.	In a 16-bed pediatric medical/surgical ICU at a tertiary care academic medical center	263 doses observed and 19% were in error. Only 6% of the doses were affected by an MAE. Common errors during administration were wrong dose, wrong time, extra dose, and wrong technique. Proximal causes of administration errors were slips and memory lapses, lack of drug knowledge, and rule violations.
Colen 2003[88]	Types of MAEs	Prospective cohort study	One phase of a study of the evaluation of a medication distribution system involving direct observation of administration. Observers would intervene if error was considered harmful to patient.	1,077 doses were observed in 1 teaching hospital in the Netherlands	The MAE rate was 27.2% including wrong time, and 7.2% excluding wrong time. The major types of MAEs included wrong time (20.0%) and omissions (3.3%).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Grasso 2003[43]	Types of MAEs	Retrospective cohort study	Review of patient records for patients discharged from the Augusta Mental Health Institute in Maine, during a period of 14 weeks	2,194 medication errors, of which 1,432 were MAEs, from 31 patient records	MAEs represented 65.3% of all medication errors. 61.9% of MAEs were due to a scheduled dose not documented as administered, 29.1% as drugs administered without an order, 8% as missed dose because of late transcription, and 3% resulting from order not being correctly entered in the pharmacy computer.
Kapborg 1999[80]	Types of MAEs	Retrospective cohort study	Analysis of malpractice cases and small interview survey with 8 nurses working in nursing homes and home care setting using semistructured questions	68 cases of MAEs occurring in several types of home care settings and nursing homes during a 4-year period, reported to a regional supervisory unit of the National Board of Health and Welfare in Sweden	The majority of MAEs made by nurses involved dosing above what was prescribed and when the drug administration was delegated to subordinate staff; the majority of MAEs involved wrong drug or wrong concentration of a drug.
Kopp 2006[45]	Types of MAEs	Prospective cohort study	Direct observation over 6 months by 2 pharmacy residents specializing in critical care pharmacy. Pharmacy residents would intervene if MAE would have resulted in patient harm.	1 16-bed medical/surgical ICU in a tertiary care academic medical center in Arizona	Overall, 27% of doses were in error. Of the 132 ADEs, 42 (32%) were attributed to medication administration. About half of those (48%) were errors of omission. Other common error types were wrong dose, extra dose, and wrong technique. Thirty seven (34%) of ADEs attributed to medication administration were considered potential ADEs, and only 3 of those were intercepted.
McCarthy 2000[86]	Types of MAEs	Cross-sectional study	Voluntary, randomly selected survey of members of the National Association of School Nurses	649 school nurses (64.9% response rate) in the United States	48.5% of respondents reported medication errors, and the majority of the types of errors were missed doses and undocumented doses.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Prot 2005[78]	Types of MAEs	Prospective cohort study	Direct observation of nurses administering medications to patients. Observers would intervene if MAE would have resulted in patient harm.	1,719 doses were observed on 4 units at a pediatric teaching hospital in Paris, France.	27% of doses were in error (538 MAEs). Wrong-time errors were 36% of MAEs, wrong route was 19%, wrong dose was 15%, and unordered drug was 10%. The risk of an MAE increased if the medication was administered by a nurse intern, a temporary staffing agency nurse, or a pool nurse (OR = 1.67, *P* = 0.03) and if the medication had been prepared by the pharmacy (OR = 1.66, *P* = 0.02).
Schneider 1998[25]	Frequency and types of MAEs	Cross-sectional	Direct observation	275 doses were observed on a pediatric ICU in Switzerland	26.9% of the doses were in error including wrong-time errors, 18.2% excluding wrong-time errors. The other common error types were wrong dose preparation and wrong administration technique.
Taxis 2003[89]	Types of MAEs in Intravenous (IV) drug administration	Cross-sectional	Ethnographic—direct observation of nurses administering medications	430 IV drug doses were observed for nurses working in 10 wards in 2 hospitals in the UK.	Overall error rate was 49%; wrong-time errors were not counted. Of the 212 errors observed, 38% involved administering a bolus dose too fast, and preparation errors accounted for 15%. Majority of preparations errors by nurses involved doses requiring multiple-step preparations, specifically preparing the wrong dose or selecting the wrong solvent.
Taxis 2003[90]	Types of MAEs in IV drug administration	Cross-sectional	Ethnographic—direct observation of nurses administering medications	22 staff nurses on 2 units in a German hospital were observed administering 122 IV doses.	Overall error rate was 48%. Wrong-time errors were not counted. Of the errors, the largest proportion occurred during a multiple-step drug preparation procedure, and the second largest was administering incompatible drugs through the same line. Majority of preparations errors by nurses involved preparing the wrong dose or selecting the wrong solvent.
Tissot 2003[91]	Type of MAEs	Prospective cohort study	Direct observation of nurses administering medications to patients by a pharmacist	Medical ICU in France	Of the 2,009 nursing acts observed, 132 (6.6%) were in error. Wrong dose was the most frequent error, followed by wrong rate of administration, errors in preparation, and physicochemical incompatibility.
Ven den Bernt 2002[94]	Frequency and type of MAEs	Cross-sectional	Direct observation of nurses administering medication to patients	233 drug administrations in 2 Dutch hospitals	Overall, 104 doses had errors (44.6%) including wrong time, 77 (33%) excluding wrong time. The most common error types were wrong dose preparation and wrong administration technique.
Wirtz 2003[37]	Types of MAEs in IV drug administration	Cross-sectional	Ethnographic—disguised observation of nurses preparing and administering medications	337 drug preparations and 278 drug administration were observed in 2 German and one UK hospital.	Across the three sites, the rate for preparation errors was 26%, and the rate for administration errors was 34%. The most common errors were wrong administration rate, omissions, and wrong dose. The types of errors varied across the hospitals, which had different pharmacy systems, although nurses prepared and administered IV meds on the wards.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Key Finding(s)
Wolf 2006[44]	Types of MAEs	Retrospective cohort study	Analysis of MAEs reported January 1, 1999, to December 21, 2003, by nursing students during the administration phase	MAEs reported by 1,305 nursing students in the USP MEDMARX program	Majority of MAEs were associated with omission (19%), wrong dose (17%), wrong time (17%), and extra dose (14%). The major causes of MAEs were reported as performance (human) deficit (51%), procedure/protocol not followed (32%), and knowledge deficit (27%). Of the reported contributing factors, 78% were due to the inexperience of staff. When an MAE occurred, 55% of the staff who made the error were informed and 44% received education/training.

Impact of Working Conditions on Medication Errors

Medication safety for patients is dependent upon systems, process, and human factors, which can vary significantly across health care settings. A review of the literature found 34 studies that investigated some aspect of working conditions in relation to medication safety.

Systems factors. Systems factors that can influence medication administration include staffing levels and RN skill mix (proportion of care given by RNs), shift length, patient acuity, and organizational climate. There were 13 articles presenting research findings and three literature reviews. The major systems/organizational factors included nurse staffing, workload, organizational climate/favorable working conditions, policies and procedures, and technologies enabling safety or contributing to MAEs.

Nurse staffing: Medication administration is a key responsibility of nurses in many settings, and three studies assessed the relationship between nurse staffing, hours of nursing care in hospitals, RN skill mix, and medication errors. Two studies associated the total hours of care and the RN skill mix at a patient care unit to reported medication error rates in those units; one study used 42 units in a large Midwestern hospital[95] and the other used 39 units in 11 small hospitals.[96] Rates of MAEs, when the number of doses was the denominator, were highest in medical-surgical and obstetric units; when patient days were the denominator, the highest rate was in ICUs. In both studies the type of unit was controlled and the rate of reported medication errors declined as the RN skill mix increased up to an 87 percent mix. A third study of nurses in ICUs in 10 hospitals found an inverse relationship between rates of medication errors and staffing work hours per patient day in specific settings (e.g., cardiac ICUs and noncardiac intermediate care settings). A little over 30 percent of the variance in medication error rates resulted from the variance in staffing work hours per patient day.[97]

Other studies conducted prior to 1998 did not find a relationship between staffing and medication errors. Three literature reviews,[30, 39, 98] concluded that the direct evidence for a relationship between staffing and MAE rates was inconsistent. Nurses' perceptions of the impact of staffing or workload on medication errors, however, is quite consistent.

Workloads: These findings are consistent with three studies and two literature reviews on the impact of heavy workloads, a component of nurse staffing, on errors. In one survey of nurses in 11 hospitals, both pediatric and adult nurses reported staffing ratios and the number of medications being administered as being the major reasons why medication errors occur.[58] A second survey found that nurses from Taiwan also indicated that workload was a major factor in medication errors.[93] Beyea, Hicks, and Becker[81, 82] and Hicks and colleagues[38] analyzed MEDMARX data for medication errors in the operating room, postanesthesia, and in same-day-surgery units. Most of these errors involved nurses (64–76 percent) and medication administration (59–68 percent). In all three sets of error reports, workload increases and insufficient staffing were noted to be causes of errors.

The effect of heavy workloads and inadequate numbers of nurses can also be manifested as long workdays, providing patient care beyond the point of effective performance. In a national survey by Rogers and colleagues,[99] self-reported errors by nurses found that the likelihood of a medication error increased by three times once the nurse worked more than 12.5 hours providing direct patient care. Among nurses working more than 12.5 hours, the reported errors, 58 percent of actual errors and 56 percent of near misses were associated with medication administration.

Other findings support the importance of adequate nurse staffing and understanding the impact of shift work in decreasing medication errors. A review of incident reports found that the major contributing factors to errors were inexperienced staff, followed by insufficient staffing, agency/temporary staffing, lack of access to patient information, emergency situation, poor lighting, patient transfers, floating staff, no 24-hour pharmacy, and code situations.[44] Certain aspects of shift work can also impact medication safety, as shown in a review of research conducted in the 1980s and early 1990s that indicated that there was a difference in the number of errors by shift, but no difference in the number of hours worked (8 versus 12 hours). However, there were more errors with nurses working rotating shifts.[30]

Organizational climate: Other systems/organizational issues include the presence of favorable working conditions, effective systems, policies and procedures, and technologies that enable safety or contribute to MAEs. An assessment of medication administration behaviors of 176 nurses in rural Australia, using structural equation modeling to test the association between organizational climate and the administration behaviors of nurses, found that the variable "violations" was the only variable with a direct contribution to MAEs, but there was no direct linkage to actual errors. While it was not possible to determine the effect of organizational climate on violations, distress was positively associated with violations, while quality of working life, morale, and organizational climate had a negative association. The organizational climate was found to be linked with safety behavior.[100] Hofmann and Mark[101] did find that the safety climate on patient care units was linked to the rate of harm-producing medication errors in a study using data collected from 82 units in 41 hospitals. Higher overall safety climate was related to lower rates of medication errors and urinary tract infections.

Policies, procedures, and protocols: Lack of appropriate policies, procedures, and protocols can impact medication safety, as seen in a few small studies. In a study of malpractice cases, medication errors were associated with lack of administration protocols and ineffective nurse supervision in delegating administration.[80] However, even when policies are in place, they may not necessarily improve safety. For example, a review of two studies in the literature found that medication errors did not necessarily decrease with two nurses administering medications (e.g., double-checking).[30] In addition, appropriate policies may not be followed. Double-checking policies are commonly used as a strategy to ensure medication safety. When errors occurred under such policies, failure to double-check doses by both pediatric and adult nurses [58] and nurses in a Veterans Affairs (VA) hospital[102] were reported. However, research presented in two literature reviews offers somewhat conflicting information. In the first review of three studies, following double-checking policies did not necessarily prevent errors.[39] Yet in the other review, failure to adhere to policies and procedures was associated with errors.[30]

Process factors. Process factors that influence medication administration include latent failures that can instigate events resulting in errors, such as administrative processes, technological processes, clinical processes, and factors such as interruptions and distractions. These factors reflect the nature of the work, including "competing tasks and interruptions, individual vs. teamwork, physical/cognitive requirements, treatment complexity, workflow."[103] A review of the literature found 18 studies and 2 literature reviews that contained process factors and their association to medication errors by nurses.

Distractions and interruptions: Factors such as distractions and interruptions, during the process of delivering care can have a significant impact on medication safety. Nine studies, four with nationwide samples, and two literature reviews present information on the association between MAEs and distractions and interruptions. One survey of nurses in three hospitals in

Taiwan found that they perceived distractions and interruptions as causes of errors.[93] In three other surveys in the United States, nurses ranked distractions as major causes for the majority of medication errors.[58, 61, 102] In a small, five-site observational study of medication administration among 39 RNs, licensed practical nurses (LPNs) and certified medical technicians/assistants (CMT/As), Scott-Cawiezell and colleagues[104] found an increase in medication errors attributable in part to interruptions, and when wrong-time errors were excluded, the error rate actually increased during medication administration.

These finding are furthered by research concerning self-reported errors from a nationwide sample of nurses.[84] The nurses believed the cause of their reported medication errors and near errors were interruptions and distractions. In a secondary analysis of the MEDMARX® data base, distractions and interruptions were prominent contributing factors to medication errors.[81–83] Furthermore, these findings are supported by three reviews of the literature: one found that distractions and interruptions interfered with preparing and administering medication, potentially causing errors;[30] interruptions were perceived as causing medication errors in the second review;[98] and the third indicated that rapid turnover and changes as well as distractions and interruptions contributed to errors.[39]

Documentation of the medication administration process: One small study investigated nurse adherence to a hospital policy to document medications administered and their effects on patients. From a sample of 12 nurses in one hospital, one-third of progress notes were found to contain information about administered medications, yet only 30 percent of those progress notes included medication name, dose, and time of administration, and only 10 percent documented information about desired or adverse effects of medications. Medication education, outcomes of administered medication, and assessment prior to administering were not documented in any progress note. Only half of withheld medications were documented.[105] In a review of records to detect medication errors, Grasso and colleagues[43] found that 62 percent did not document doses as administered.

Communication: Five studies and one literature review assessed the relationship between communication failures and medication errors. A small observational study of 12 nurses found that they communicated with other nurses about information resources on medications, how to troubleshoot equipment problems, clarification in medication orders, changes in medication regimens, and patient assessment parameters when handing over patients.[106] Nurses communicated with physicians informally to exchange information, about the absence of other physicians, and in both unstructured and structured ward rounds. Nurses also communicated with pharmacists about information on medication administration and organizing medications for patient discharge. Another direct observational study of medication administration found opportunities for errors associated with incomplete or illegible prescriptions.[91] This finding was supported by two related literature reviews that indicated that illegible and poorly written drug prescriptions and breakdowns in communication led to errors.[30, 39] Another survey found that nurses ranked difficult/illegible physician handwriting as a cause of the majority of medication errors, but did not consider withholding a dose because a lab report was late or omitting a medication while the patient was sleeping as something that should have been communicated to physicians or others.[61]

A small survey of 39 nurses in three hospitals in Nova Scotia about communication failures during patient transfers found that more than two-thirds of nurses reported difficulty in obtaining an accurate medication history from patients when they were admitted; 82 percent reported patients were unable to provide accurate medication histories. When patients were transferred

from across units, 85 percent of nurses reported that medication orders were rewritten at transfer, 92 percent that medication orders were checked against electronic medical records, 62 percent that it was time consuming to clarify medication orders, 66 percent that the reasons for medication changes were made at transfer, and 20 percent that blanket orders are often written as transfer orders.[107]

Complexity: Three studies investigated the impact of complexity on medication safety. In a small, five site observational study of medication administration of 39 RNs, LPNs and CMT/As in long-term care settings, Scott-Cawiezell and colleagues[104] found that even though RNs administered fewer medications they had more MAEs, compared to LPNs and CMT/As. The suggested explanation was that the mediations RN must administer in long-term care are those with more complexity. Another survey of 284 RNs in 11 hospitals found that pediatric and adult nurses reported numbers of medications being administered as a major reason on why medication errors occur.[58] Also, another survey of nurses found that they perceived that complicated doctor-initiated orders (24 percent) and complicated prescription were the major causes of MAEs related to the medication administration process.[93]

Equipment failure while administering medication: Three studies found that systems and process factors can interfere with medication administration when equipment used in administration does not perform properly, exposing the nurse and patient to safety risks. In two ICU studies, infusion pump problems were involved in 6.7 percent of 58 MAEs in one study[24] and 12 percent of the 42 MAEs in the other sutdy.[45] Another investigation of smart pumps with integrated decision-support software found that half of the ADEs were considered preventable (2.12 of 100 patient-pump days), and 72 percent of preventable ADEs were serious or life-threatening.[108] Given the number of ADEs, the fact that the drug library was bypassed in 24 percent of the infusions, and the frequency of overriding alerts, the investigators concluded that use of the smart pumps did not reduce the rate of serious medication errors—but possibly could if certain process factors could be modified, such as not allowing overrides.

Monitoring and assessing: An essential component of the medication process related to the administration of medications is monitoring and assessing the patient by the nurse. Only two studies provided information in this area, offering scant evidence. In the first, based on a small sample of nurses in one unit in one hospital, a qualitative analysis of observed medication administration found that participants monitored patients before, during, and after medication administration.[109] Nurses assessed vital signs, lab values, ability to swallow, and patients' self-report of health. They also felt responsible for timing medication administration and providing as-needed (e.g., PRN) medications. In the second study, where ICU nurses were surveyed, no administration errors were found to be associated with inadequate monitoring or lack of patient information.[24]

Effects of Human Factors on Medication Administration Errors

There are a wide range of system-related human factors that can impact medication administration. These factors include characteristics of individual providers (e.g., training, fatigue levels), the nature of the clinical work (e.g., need for attention to detail, time pressures), equipment and technology interfaces (e.g., confusing or straight-forward to operate), the design of the physical environment (e.g., designing rooms to reduce spread of infection and patient falls), and even macro-level factors external to the institution (e.g., evidence base for safe practices, public awareness of patient safety concerns).[103] There were 10 studies that assessed the

association of human factors with MAEs. Four major themes emerged in the review: fatigue, cognitive abilities, experience, and skills.

Effects of fatigue and sleep loss: Five studies assessed the association between fatigue and sleep loss with MAE errors. The first specifically investigated the effects of fatigue and sleep loss on errors using a national sample of nurses over a 2-week period. In this study, the rate of errors increased after working 12.5 hours.[99] A subpopulation of critical care nurses reported forgetfulness, heavy workload, distractions, and high patient acuity as causes for their medication errors or near errors.[84] Fatigue and sleep loss was also a factor in a subpopulation of ICU nurses, who reported errors with high-alert medications (e.g., morphine, chemotherapeautic agents).[85] The other two studies assessed fatigue along with other variables associated with medication errors. In one of these, a survey of 57 nurses, respondents reported that the majority of medication errors were attributable to fatigue.[70] The other study, a survey of 25 nurses in one hospital, found that one of the most frequently perceived causes of medication errors for nurses was being tired and exhausted (33.3 percent).[102]

The thought processes of nurses during medication administration was assessed in two studies. A semistructured, qualitative interview of 40 hospital nurses prior to implementation of a bar-coding system explored the thinking processes of nurses associated with medication administration.[110] Their thought processes involved analyzing situations and seeking validation or a solution when communicating about patients; using knowledge, experience, and understanding of patients' responses to anticipate problems; integrating their knowledge of lab values and patterns of pathophysiological responses to determine possible need to change dosage or administration timing; checking orders for validity and correctness; assessing patients' responses for possible side effects and effectiveness of the drug; using cues from patients or family members about need for explanations about drugs; bypassing protocols or procedures, some taking a risk, to get drugs to patients or use time more efficiently; anticipating needs for future problem solving; and applying professional knowledge during drug administration. The other study of nurses, using direct observation in a medical and surgical unit in Australia, found that participants used hypothetico-deductive reasoning to manage patient problems.[111] Graduate nurses used pattern recognition of patient characteristics and medications during decisionmaking. Intuition and tacit knowledge was used in relation to changes in patients' vital signs and to objectively monitor patients.

Thought process can also be distorted by distractions and interruptions. One study employed direct observation of medication administration to determine the effects of human factors on MAEs.[24] The investigators found that slips and memory lapses were associated with 46.7 percent of MAEs. During both the prescribing and administration of medications, the causes of errors were attributable to slips and memory lapses (23.1 percent during prescribing vs. 46.7 percent during administration), lack of drug knowledge (46.2 percent during prescribing vs. 13.3 percent during administration), and rule violations (30.8 percent during prescribing vs. 13.3 percent during administration). Another study using direct observation found causes associated with MAEs to include slips and memory lapses (40 percent), rule violations (26 percent), infusion pump problems (12 percent), and lack of drug knowledge (10 percent).[45]

Experience and skills also impact thought processes. In one study of 40 student nurses and 6 nurses using a computerized program to assess the impact of dyslexia found that the greater the tendency towards dyslexia, the poorer the potential cognitive ability to effectively provide the skills associated with effective drug administration.[112] Similarly, in two reviews of the literature,

a number of medications errors were found to be caused by poor mathematical skills,[30] especially if mathematical skills were needed to properly administer drugs.[39]

Lack of medication knowledge is a constant problem, and there is a need to continually gain more knowledge about current and new medications.[30] Nurses with more education and experience may have greater knowledge of medications.[39] However, experience has not been found to mitigate the effect of poor mathematical skills nor frequency of MAEs.[30] Those new to a unit or profession may be at risk for errors.[39] In a survey of nurses working in three hospitals in Taiwan, nurses reported causes of MAEs as new staff (37.5 percent), unfamiliarity with medication (31.9 percent), unfamiliarity with patient's condition (22.2 percent), and insufficient training (15.3 percent).[93] Inexperience may also contribute to performance (human) deficit, willingness to follow a procedure/protocol, and knowledge deficit. Of these reported contributing factors, 78 percent were due to the inexperience of staff.[44] Blegen, Vaughn, and Goode[113] found that medication errors rates were inversely related to the proportion of nurses on a unit with greater experience, but were not related to the educational level of the staff on the unit.

Evidence Table 2. Working Conditions Associated With Medication Administration Errors and Adverse Drug Events

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Aitken 2006[105]	*Process Factors*: Documentation of medication administered by nurse	Cross-sectional study	Review of patient medication charts and progress notes for one working shift. Each participant was interviewed.	47 nurses in one urban teaching hospital in Australia	None	34% of progress notes contained information about administered medications. 30% of progress note entries included medication name, dose, and time of administration. Medication education was not documented in any progress note. Outcomes of administered medications were not documented, nor was assessment prior to administering. 10% of progress notes documented information about desired or adverse effects of medications. Only half of withheld medications were documented.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Armitage 2003[39]	*System Factors:* Workload *Process Factors:* Lack of double-checking Failure to follow policies and procedures Distractions and interruptions Communication processes *Human Factors:* Individual characteristics and abilities associated with medication administration errors (MAEs)	Literature review	Expanded upon the O'Shea (1999)[30] review	Literature on drug administration, drug error, and nursing was reviewed.	None	Workload—4 studies indicated equivocal findings on the relationship between workload and errors. Lack of double-checking—3 studies indicated that double-checking did not necessarily prevent errors. Failure to follow policies and procedures—6 studies indicated that failure to adhere to policies has been associated with errors. Distractions and interruptions—6 studies indicated that rapid turnover and changes as well as distractions and interruptions contributed to errors. Communication failures—7 studies indicated that illegible and poorly written drug prescriptions led to errors. Mathematical skills of nurses—5 studies indicated that poor mathematical skills may put nurses at risk for errors, especially if they need complex mathematical skills to administer drugs. 3 additional studies indicated weight-base dosing and mathematical calculations of dosing resulted in potential risk of errors. Knowledge of medications—3 studies indicated that knowledge of medication may be greater in nurses with more education and experience. Length of nursing experience—6 studies indicated that those new to a unit or profession may be at risk for errors.
Balas 2006[84]	*System Factors:* Workload and staffing *Process Factors:* Distractions and interruptions	Cross-sectional	Qualitative 14-day self-reported record of shift work and errors	502 RNs in critical care units	None	Nurses reported forgetfulness, heavy workload, distractions, and high patient acuity as causes for their medication errors or near errors.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Beyea 2003[81]	*System Factors:* Workload and staffing *Process Factors:* Distractions and interruptions *Human Factors:* Experience	Secondary analysis	179 reported medication errors in same-day surgery	MEDMARX® data	None	Workload increase in 11.2% reports, insufficient staffing in 8.4%. Distraction associated with 56.4% of errors. Inexperienced staff with 14.5% of error reports.
Beyea 2003[82]	*System Factors:* Workload and staffing *Process Factors:* Distractions and interruptions *Human Factors:* Experience	Secondary analysis	731 reported medication errors in the operating room	MEDMARX® data	None	Workload increase in 11.5% reports, insufficient staffing in 4.8%. Distraction associated with 48% of errors. Inexperienced staff with 17% of error reports.
Blegen 1998[95]	*System Factors:* Staffing and RN skill mix	Cross-sectional	Administrative data for nurse staffing and medication errors at the patient care unit level	42 units in 1 large tertiary care hospital	None	Rates of medication errors were inversely associated with RN skill mix up to an RN proportion of 87.5%. Rates of medication errors were positively correlated with falls (0.192).
Blegen 1998[96]	*System Factors:* Staffing and RN skill mix	Cross-sectional study	Analysis of event reports and nurse staffing patterns for 10 quarters	39 units in 11 hospitals	None	Rates of MAEs by 10,000 doses were highest in medical-surgical and obstetric units; they were highest by 1,000 days in ICUs. Units with RN proportions greater than 85% had higher rates of MAEs per 10,000 doses.
Blegen 2001[113]	*Human Factors:* RN education and experience	Cross-sectional study	Secondary data analysis	80 units in 12 hospitals	None	MAEs were inversely related to RN experience but were not related to RN education.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Buckley 2007[24]	*Process Factors*: Communication processes Medication administration process *Human Factors:* Individual characteristics associated with MAEs	Prospective cohort study	Anonymous survey of pediatric ICU nurses about the medication process, followed by a direct observation over 6 months of medication process, determining actual and potential errors. Observers of medication administration would intervene if error was considered harmful to patient.	In a 16-bed pediatric medical/surgical ICU at a tertiary care academic medical center	None	Faulty interaction with other services (6.7%) and infusion pump problems (6.7%); no administration errors were found to be associated with drug stocking and delivery, inadequate monitoring, or lack of patient information. Majority of MAEs were associated with slips and memory lapses (46.7%), lack of drug knowledge (13.3%), rule violations (13.3%).
Carlton 2006[98]	*System Factors*: Length of work shift Staff skill mix Patient acuity *Process Factors*: Interruptions Unclear orders Medications received late *Human Factors*: Skill/education/ experience Knowledge of medications	Literature review	Medication administration literature published before 2005		None	5 studies reviewed the association of nurse skill mix with MAEs; found that the research on skill mix is conflicting. 1 study reviewed a neonatal care unit and found increasing number of medication errors (MEs) associated with increasing acuity of newborns. Many MAEs are not recognized as an error. 1 study of a cross-sectional survey of nurses found that nurses perceived MEs to be caused by late arrival of medications from pharmacy, RNs too busy, RNs forgetful or failure in oversight, and unclear medical administration records. 1 study found lack of knowledge and skill/experience, failure to adhere to policies and procedures, and communication failures as active errors by nurses resulting in MEs.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Chevalier 2005[107]	*Process Factors*: Nurse management of the medication administration process	Cross-sectional study	Retrospective survey on safety culture	39 nurses (35% response rate) in 3 hospitals in the Capital Health district of Nova Scotia	None	69% of nurses reported difficulty in obtaining an accurate medication history from patients when they were admitted; 82% reported patients were unable to provide accurate medication histories (e.g., reconciliation). When patients were transferred from another unit, 85% of nurses reported that medication orders were rewritten at transfer, 92% that medication orders were checked against electronic medical records, 62% that it was time consuming to clarify medication orders, 66% that the reasons for medication changes made at transfer, and 20% that "blanket" orders are often written as transfer orders.
Eisenhauer 2007[110]	*Human Factors:* Individual characteristics associated with MAEs	Cross-sectional study	Semistructured, retrospective, qualitative interview of nurses; then used basic content analysis of the narrative data.	40 staff nurses in one northeastern U.S. hospital where bar-coding was being implemented	None	Nurses' thought processes in relation to medication administration included - Analyzed situations and sought validation or a solution when communicating about patients. - Used knowledge, experience, and understanding of patients' responses to anticipate problems. - Integrated their knowledge of lab values and patterns of pathophysiological responses to determine possible need to change dosage or administration timing. - Checked orders for validity and correctness. - Assessed patients' responses, the possible presence of side effects, and effectiveness of drug. - Used cues from patients or family members about need for explanations about drugs. - Bypassed protocols or procedures, some taking a risk, to get drugs to patients or use time more efficiently. - Anticipated need for future problem-solving. - Applied professional knowledge during drug administration.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Fogarty 2006[100]	*System Factors:* Organizational climate	Cross-sectional study	Survey included a 6-item quality of work life, satisfaction with working conditions, positive and negative affect, organizational climate, and a procedure violation scale.	176 nurses in rural Australia working in 11 public sector hospitals	None	"Violations" was the only variable with a direct contribution (24%) to MAEs. Distress was positively associated with violations, while quality of working life, morale, and organizational climate had a negative association. It was not possible to determine if the effect of organizational climate on violations is direct or mediated by stress and morale, but organizational climate is linked with safety behavior.
Hicks 2004[38]	*System Factors:* Workload and staffing *Process Factors:* Distractions and interruptions *Human Factors:* Experience	Retrospective cohort study	645 reported medication errors in postanesthesia care unit	MEDMARX® data	None	Workload increase in 15.5% reports; insufficient staffing in 4.3%. Distraction associated with 47% of errors. Inexperienced staff associated with 14.9% of error reports.
Hofmann 2006[101]	*System Factors:* Safety climate	Cross-sectional study	Survey and administrative data from 82 units in 41 hospitals		None	Increased safety climate scores associated with lower rate of medication errors causing harm.
Kapborg 1999[80]	*Process Factors:* Policies and procedures Supervision Documentation of administration	Retrospective cohort study	Analysis of malpractice cases and small interview survey with 8 nurses working in nursing homes and home care setting using semistructured questions	68 cases of MAEs occurring in several types of home care and nursing home settings	None	Reported causes of MAEs were lack of administration protocols, failure to check orders, ineffective nurse supervision in delegating administration, and inadequate documentation.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Kopp 2006[45]	*Process Factors:* Equipment malfunction during medication administration *Human Factors:* Individual characteristics associated with MAEs	Prospective cohort study	Voluntary survey of nurses on the medication use process followed by direct observation over 6 months by 2 pharmacy residents specializing in critical care pharmacy. Pharmacy residents would intervene if MAE would have resulted in patient harm.	1 16-bed medical/surgical ICU in a tertiary care academic medical center in Arizona	None	12% of the 42 MAEs were caused by infusion pump problems. Causes associated with MAEs included slips and memory lapses (40%), rule violations (26%), lack of drug knowledge (10%).
Manias 2004[109]	*Process Factors:* Medication management and patient monitoring	Prospective cohort study	Qualitative participant observation and questioning of nurses during medication administration	12 graduate nurses in medical and surgical units of a university teaching hospital in Melbourne, Australia	None	To monitor patients before, during, and after medication administration, nurses assessed vital signs, lab values, ability to swallow, and patient self-report of health. Participants felt responsible for timing medication administration and providing as-needed medications.
Manias 2004[111]	*Human Factors:* Cognitive reasoning	Prospective cohort study	Qualitative participant observation of nurses during medication administration	12 graduate nurses in medical and surgical units of a university teaching hospital in Melbourne, Australia	None	Participants used hypothetico-deductive reasoning to manage patient problems. Graduate nurses used pattern recognition of patient characteristics and medications during decisionmaking. Intuition and tacit knowledge was used in relation to changes in patients' vital signs and objective monitoring of patients.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Manias 2005[114]	*Process Factors:* Communication with health care providers	Prospective cohort study	Qualitative participant observation of nurses during medication administration	12 graduate nurses in medical and surgical units of a university teaching hospital in Melbourne, Australia	None	Nurses communicated with other nurses about information resources on medications, how to troubleshoot equipment problems, clarification in medication orders, changes in medication regimens, and patient assessment parameters when handing over patients. Nurses communicated with physicians informally to exchange information, about the absence of other physicians, and in both unstructured and structured ward rounds. Nurses communicated with pharmacist about information on medication administration and organizing medications for patient discharge.
Manias 2005[106]	*Process Factors:* Adhering to protocols for medication administration	Prospective cohort study	Qualitative participant observation of nurses during medication administration	12 graduate nurses in medical and surgical units of a university teaching hospital in Melbourne, Australia	None	Protocols were used to check that practices were acceptable, obtain information on medications, provide patient care without seeking additional information from physicians, and provide key information when working in another unit. Nurses examined the patient's identity 27% of the time before medication administration; double-checked certain medications before administration with another nurse 80% of the time; did not complete incident reports for medication errors (only 2 medication errors were observed); sought information on unfamiliar medications 86% of the time; sought clarity on unclear medication orders 100% of the time; and observed patients taking oral medications 90% of the time.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mayo 2004[61]	*Process Factors:* Lack of order clarity Communicating missed doses	Cross-sectional study	Random sample of RNs surveyed about perceived causes of medication errors; percentage of medication errors reported to nurse managers; types of reportable incidents; and reporting behaviors, including medication errors scenarios.	983 RNs (a 20% response rate) in the United Nurses Association of California/Union of Health Care Professionals		Nurses ranked difficult/illegible physician handwriting, distractions, and being tired and exhausted as causes for the majority of medication errors. Nurses would not communicate to physicians or others when a routine morning dose of medication was withheld because a lab report was late (91.8%) or a dose omitted while the patient was sleeping (55.5%).
Millward 2005[112]	*Human Factors:* Cognitive skills involved in drug administration	Prospective cohort study	Used a computerized program to assess the presence of dyslexia and its effects on drug administration skills	40 students and 6 qualified nurses	None	The greater the tendency to dyslexia, the poorer the potential cognitive ability to effectively provide skills associated with drug administration.
Osborne 1999[70]	*Process Factors:* Distractions Failure to comply with procedures *Human Factors:* Confusion Fatigue	Cross-sectional study	Self-reported perception of nurses on medication errors, their causes, and how medication errors should be reported	57 full-time and part-time RNs (a 62% response rate) in a medical-surgical unit in a 700-bed community hospital in south Florida		Main cause of medication errors was failure to identify the right patient (35.1%), and 24.6% indicated the effects of fatigue.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
O'Shea 1999[30]	*System Factors:* Workload Nurse staffing Medication delivery systems *Process Factors:* Shift and hours worked Single nurse drug administration Adherence to policy and procedures Distractions and interruptions *Human Factors:* Mathematical skills Knowledge of medications Experience	Literature review	Retrospective review of 97 articles published in 1995 and earlier, involving the definition and contributing factors to MAEs	Studies involving nurses and medication administration	None	Staffing—2 studies indicated contradictory implications on the effect of staffing levels on the incidence of medication errors. Shift and hours worked—3 studies indicated that there was a difference in the number of errors by shift; and 2 studies indicated that there was no difference in the number of hours worked (8 vs. 12), but there were more errors with nurses working rotating shifts. Workload—3 studies indicated that the effect of a heavy workload can be compounded by distractions; use of temporary staff and inadequate skill mix are associated with more errors. Medication delivery systems—1 study indicated that the error rate was higher in units using a medication nurse to administer medications. Single nurse drug administration—2 studies indicated that medication errors did not necessarily decrease with two nurses administering medications (e.g., double-checking). Adherence to policy and procedures—8 studies indicated that MAEs can be caused by failure to adhere to policies. Distractions and interruptions—5 studies indicated that distractions and interruptions interfere with preparing and administering medication, potentially causing errors. Mathematical skills—8 studies indicating that a number of medications errors are caused by poor mathematical skills. Knowledge of medications—8 studies indicated that not only is lack of knowledge a constant problem, but there is a need to continually gain more knowledge about current and new medications.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
O'Shea 1999[30] (cont.)						Length of experience—2 studies indicated that experience did not mitigate the effect of poor mathematical skills nor frequency of MAEs
Rogers 2004[99]	*System Factors:* Nurse staffing Shift work	Cross-sectional study	Qualitative 14-day self-reported record of shift work and errors	Nationwide sample of 393 nurses (a 40% response rate)	None	The risk of medication administration errors was nearly three times higher once a nurse worked more than 12.5 hours during a 24-hour period. In over 80% of shifts, nurses reported leaving after their scheduled shift, working on average 55 minutes longer than scheduled each day. Work duration, overtime, and number of hours worked in a week was directly associated with errors.
Rothschild 2005[108]	*Process Factors:* Using smart pumps to decrease medication administration errors	Randomized clinical trail	Prospective, randomized time-series trial comparing the rate of serious medication errors with and without decision support during 11 months.	1 cardiac surgical intensive care and 2 step-down units in a hospital in Boston	Implementation of new intravenous infusion pumps with decision support (i.e., alerts, reminders, and unit-specific drug rate limits) used during medication administration	During the trial, half of ADEs were preventable (2.12 of 100 patient-pump days); 72% of preventable ADEs were serious or life-threatening. During the intervention, bypassing the drug library (24% of infusions) and overriding alerts were frequent. Use of the smart pumps did not reduce the rate of serious medication errors.
Scott-Cawiezell 2007[104]	*Process Factors:* Distractions and interruptions	Prospective cohort	Naïve, direct observation of medication administration	8 RNs, 12 LPNs, 19 CMT/As in 5 Midwestern nursing homes	None	RNs administered 15.3% of observed doses, LPNs 23.3%, and CMT/As 61.43%. The MAE rate for RNs was 34.6%, LPNs 40.1%, and CMT/As 34.2%. RNs had more interruptions (39.9%), and LPNs had more distractions (41.6%).
Stratton 2004[58]	*System Factors:* Workload *Process Factors:* Distractions and interruptions	Cross-sectional study	Nurses were surveyed to assess the perceived causes of MAEs.	284 RNs (227 adult and 57 pediatric nurses) in 11 hospitals in 2 States (40% response rate)	None	Pediatric and adult nurses reported distractions and interruptions (50% of pediatric nurses and 47% of adult nurses), RN-to-patient ratios (37% and 37%), numbers of medications administered (35% and 31%), and not double-checking doses (28% and 28%) as the most important causes of MAEs.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Tang 2007[93]	*System Factors:* Workload *Process Factors:* Complicated orders Distractions and interruptions *Human Factors:* Experience Knowledge and skills	Cross-sectional study	A semistructured questionnaire was used to assess MAE events, background of the nurse, and perceived contributing factors.	72 female nurses at 3 acute care hospitals (80% response rate)	None	Nurses reported personal neglect (86%), heavy workload (38%), complicated doctor-initiated order (24%), and complicated prescription as the major causes of MAEs related to the medication administration process. Personal neglect included distraction, interruptions, not double-checking, and poor mood. Nurses reported causes of MAEs as new staff (37.5%), unfamiliarity with medication (31.9%), unfamiliarity with patient's condition (22.2%), and insufficient training (15.3%).
Tissot 2003[91]	*System Factors:* Workload *Process Factors:* Incomplete/illegible orders	Prospective cohort study	Direct observation of nurses administering medications to patients by a pharmacist	A geriatric unit and a cardiovascular-thoracic surgery unit within a hospital in France	None	Opportunities for errors were associated with incomplete/illegible prescriptions and nurse workload (OR = 2.44, 95% CI = 1.30–4.60; *P* = 0.006).
Ulanimo 2007[102]	*Process Factors:* Perceived causes of MAEs *Human Factors:* Distractions	Cross-sectional study	Survey on perceived causes of medication errors and percentage of all medication errors that are reported to the nurse manager, completing an incident report.	25 nurses (44% response rate) in a VA hospital in Northern California	None	The most frequent perceived causes of medication errors for nurses were failing to check patient name band with medication administration record (45.8%); being tired and exhausted (33.3%); miscalculating the dose (29.2%); confusion between 2 look-alike drugs (29.2%); distractions (25%); different infusion devices being used (25%); unclear medication labeling/packaging (25%); and wrong infusion device set up/adjustment (24%).
Whitman 2002[97]	*System Factors:* Nurse staffing	Prospective cohort study	Secondary data analysis of a prospective, observational cohort study	95 patient care units in 10 adult acute care hospitals in an integrated health care system in the eastern United States	None	Rates of medication errors were inversely associated to staffing work hours per patient day in cardiac ICU (r = -0.53) and noncardiac intermediate (r = -0.55) care settings. 30.3% of the variance in medication error rates resulted from the variance in staffing work hours per patient day.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Wolf 2006[44]	*Process Factors:* Distractions *Human Factors:* Knowledge deficit Inexperience	Retrospective cohort study	Analysis of MAEs reported January 1, 1999, to December 21, 2003, by nursing students during the administration phase	MAEs reported by 1,305 nursing students in the USP MEDMARX® program; 763 reports included contributing factors.	None	The major contributing factors to MAEs were inexperienced staff (78%) and distractions (20%). The other, significantly fewer causes of errors were insufficient staffing, agency/temporary staffing, lack of access to patient information, emergency situation, poor lighting, patient transfer, floating staff, no 24-hour pharmacy, and code situation. The major causes of MAEs were reported as performance (human) deficit (51%), procedure/protocol not followed (32%), and knowledge deficit (27%).

Strategies To Improve Medication Administration Safety

Strategies to improve medication safety focused on acute care settings. Twenty-six studies and descriptions of quality improvement projects were identified. Strategies used included recommendations from a nationwide voluntary organization to improve safety, education of nurses and other providers in safe practices, and system change and technology.

Nationwide voluntary efforts. Lucian Leape and colleagues[116] reported on a 15-month Institute for Healthcare Improvement Breakthrough Series Collaborative intended to reduce ADEs. Eight types of strategies were successfully used, including documentation of allergies, nonpunitive reporting, and standardizing medication administration times. Effective leadership and appropriateness of intervention were associated with successful change implementation. The converse was associated with failure, as were unclear aims, poorly designed interventions, lack of focus on underlying system failures, unclear measures, too much focus on data collection, involvement from only some stakeholders, opposition from physicians and nurses, and conflicting time demands for team members. The findings were limited by the lack of an analysis of the relationship between established safety policies and practices and the success of implementing new strategies, as well as the relationship between the implementation and the occurrence of ADEs.

A survey of 148 hospitals about the characteristics and barriers associated with adoption of the National Quality Forums' 30 safe practices was done by Rask and colleagues.[117] These practices included unit dosing, adopting computerized physician order entry (CPOE), and having a culture of safety. Of the recommended practices, there was high adoption of standardized labeling and storage of medications (90.5 percent), identification of high-alert medications (81 percent), and use of unit doses (81 percent). For-profit hospitals were more likely than not-for-profit hospitals to have unit-dose medication distribution systems (93.1 percent vs. 78.2 percent) and policies on reading back verbal orders (83.1 percent vs. 58.4 percent). There were greater distractions affecting medication administration in large hospitals. Hospitals with 100–299 beds were more likely to report using pharmacists to review and approve nonemergency orders prior to dispensing; and, 69.4 percent of all hospitals used data analysis to drive patient safety quality improvement efforts.

Nurses' education and training. Educational strategies aimed to improve medication safety and avert unnecessary medication errors. One randomized controlled study used an interactive CD-ROM education program to improve the use of safe medication practices and decrease the rate of MAEs.[118] Direct observation of medication administration was used to assess the impact. After the training, nurses' use of safe administration practices increased, but preparation errors did not decrease. There were too few actual medication errors to analyze pre-post differences. Another approach used an 11 module Web-based educational strategy to improve drug safety with a small sample of nurses.[119] Direct observation of medication administration was used to determine the outcome. After using these modules, rates of nonintravenous MAEs decreased from 6.1 percent to 4.1 percent. Rates of errors in intravenous drug administration did not decline as expected. Dennison[120] reported the results of a medication safety training program for nurses. Knowledge scores improved in this pre-post test study, but there was no significant change in safety climate scores, labeling of intravenous infusion setups, or the number of self-reported errors.

Attempts to improve basic and continuing education in medication safety have been reported, but they have not assessed the impact on actual error rates. In a small pilot study, a problem-

based learning approach was found to enable students to use findings from topic-specific research to develop and apply solutions for clinical problems. Papastrat and Wallace[121] proposed using problem-based learning and a systems approach to teach students how to prevent medication errors and suggested content, but their approach was not compared to other teaching methods. Another proposed educational strategy for practicing nurses was to use simulation of medication administration and errors in a controlled setting to improve medication safety, "duplicate the complexity of the nurse-patient interaction and related cognitive thought"[122] (p. 249). Simulations could be used to prepare nurses to recognize and manage medication errors when and if they occur.

System change. Several attempts to change the system have been tested. Some of the strategies addressed the thoroughness of error reporting, some the processes and events surrounding medication administration, and some focused directly on reducing errors. Using a hospitalwide performance improvement project that emphasized system factors, not individual blame, error reporting increased from a rate of 14.3 percent to 72.5 percent.[123] To address intravenous infusion problems, a medication safety education program and medication calculation worksheets were introduced, followed by ongoing Plan-Do-Study-Act cycles.[124] Multiple system changes were also used to improve safety of intravenous drug infusion. These included removing 90 to 95 percent of potassium chloride ampoules from the bedside; developing preprinted labels for five common drug infusions; removing four-channel infusion pumps the unit and replacing them with double-channel infusion pumps with a simple interface design; standardizing administration of drugs given by bolus dose using a syringe pump; decreasing missed doses of immunosupression drugs for transplant patients from 25 percent to 9 percent by incorporating them into the main drug chart; implementing standardized prefilter and heparin-lock central venous catheters and heparin infusions into ICU protocol; redesigning drug infusion administration practices throughout the hospital; eliminating burettes for IV drug infusion; preparing standardized drug infusions for 36 drugs; and providing Intranet-based up-to-date drug information.

A time study and focus groups were used to compare nurse efficiency during medication administration using either medication carts with unit doses or a locked wall-mounted cupboard in each patient room.[125] After 12 weeks, the wall-mounted units were found to have decreased medication administration time for nurses an average 23 minutes per 12-hour shift. Time saved by not having to search for missing medications saved 0.38 full-time equivalent (FTE) annually. Pharmacists spent an additional 0.05 FTE in stocking room cupboards. Nurses reported more contact time with patients when using room cupboards and fewer interruptions by colleagues during medication preparation and administration. Two small experimental studies attempted to reduce distractions that frequently interrupt nurses during medication administration and thereby introduce the potential for error.[126, 127] In both studies a standardized protocol for safe administration of medications was introduced to the nursing staff in the experimental group and signage was used to remind others (physicians, patients, other staff) to not interrupt. The signage in the first study was a vest that the nurse administering medication wore; in the second it was a sign above the preparation area. Direct observation of the number and types of distractions provided the outcome measures in the first study; a questionnaire completed by each nurse administering medications provided the measure of distractions for the second. In both studies, the number of distractions was significantly reduced. Medication error rates were not captured.

One randomized controlled trial compared the use of a dedicated nurse for medication administration to nurses providing comprehensive care, including administering medications, to

their patients in two hospitals.[128] MAEs were then assessed using direct observation. The investigators found the error rates to be 15.7 percent at the intervention hospital and 14.9 percent in the control hospital. The rate of MAEs was not significantly different between control and experimental groups.

Involving patients in the administration of medications while in the hospital is another system strategy that has been assessed. With this intervention, hospitalized patients have the responsibility for administering their own medication under the supervision of nursing staff. A literature review reported on 12 studies that described and evaluated a patient self-administration program.[129] This review found that the patients' knowledge about their medications and the prescribed dosing increased, but knowledge about the potential side effects of their medications did not. Given the body of the reviewed literature, it appeared as though patients and families make as many or more MAEs than do health care providers.

System change with technology. Another rapid-cycle implementation project over 6 months used continuous quality improvement data before and after implementing a modular, computerized, integrated infusion system.[130] Most infusion error warnings occurred between 3 p.m. and 9 p.m., peaking at 6 p.m. Nurses responded to 12 percent of the infusion error warnings by altering the setting and averting errors. The nature of the 88 percent of warnings not responded to was not discussed. Risk scores associated with heparin infusion rates decreased almost fourfold. Almost all nurses used the new software correctly.

Two studies focused on documentation of medication administration. One study introduced a charting system with decision support and used a quasi-experimental design to determine the effects.[131] Researchers collected medication charting data for 8 weeks in both the control and study units. Staff in the study unit received an educational intervention about error avoidance through real-time bedside charting, followed by 12 weeks of monitoring and performance feedback. After the 12 weeks, medication charting rates increased from 59 percent to 72 percent in the intervention group. The second study used a computer-based "unreported meds followup" to remind nurse staff about scheduled medications omitted or not documented.[132] After charts were prospectively reviewed, a mandatory medication error prevention seminar was given to nurses, and a medication review report was created for nurses. Reported medication errors and documentation of medication administration were reviewed, medication administration policies were developed, and focus changed to the potential causes of errors. Documentation errors decreased over the 3 years of the study, and reported error rates increased by 0.5 percent each year.

Bar-coded medication administration (BCMA) is promoted as the most effective way to reduce administration errors and is being implemented widely. Conceptually this technology should catch nearly all errors, but rigorous evaluation of the impact of technology on error rates has lagged behind implementation. The biggest challenge to determining the effectiveness of BCMA or other interventions is the lack of valid measures of MAEs. Data from voluntary self-reported medication errors are known to capture only a small portion (5 percent to 50 percent) of actual errors, and the BCMA system itself greatly alters nurses' awareness of errors, thereby systematically affecting reported error rates. Many studies reporting analysis of the impact of BCMA have used data collected by the system only after implementation.[133–136] From these we learn the types of errors intercepted by the system. Three other studies of the impact of BCMA on administration errors reported very large reductions: 59–70 percent decrease,[137] 71 percent and 79 percent drops.[138] However, the sources of the data for determining these decreases are not known.

Direct observation of medication administration, a resource- and time-intensive approach to data collection, is the only way to gather unbiased data to evaluate the impact of BCMA on medication administration errors. Three studies have used direct observation; however, each evaluated the implementation of a different set of technology. Franklin and colleagues[139] reported a decline in MAE rates from 8.6 percent to 4.4 percent when a new system was implemented in a teaching hospital in England. The system included BCMA, computerized order entry, automated dispensing, and electronic medication administration record. Prescription errors also declined from 3.8 to 2 percent. It is noteworthy that the rate of both administration and prescribing errors by direct observation was much lower than other direct observation studies have reported. Paoletti and colleagues[140] used direct observation to determine the impact of BCMA and an electronic medication record in a hospital in the United States. They reported that the rate of MAEs declined from 13.5 percent to 3 percent. Finally, the implementation of only the electronic medication administration record led to a decline in MAEs from 10.5 percent to 6.1 percent using direct observation.[141] Health-related technology designed to increase medication safety has great promise, but more study using valid outcome measures and controlled interventions needs to be done to demonstrate the potential benefits.

Evidence Table 3. Strategies To Reduce Medication Administration Errors

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Anderson 2004[137]	Bar-coded technology	Quality improvement project		One hospital	Bar-coded point-of-care medication administration	59%–70% reduction in MAEs. Positive effect on nurses' satisfaction.
Bennett 2006[125]	Dispensing mechanisms to improve medication administration	Quality improvement project	Time study and focus groups to compare nurse efficiency using medication carts or a unit dose to locked wall-mounted cupboards in each patient room	Nurses in 2 units and pharmacists in one hospital	Wall-mounted cupboards in patient rooms	Wall-mounted units decreased medication administration time for nurses an average 23 minutes per 12-hour shift. Time saved not searching for missing medications saved 0.38 FTE annually. Pharmacist spent an additional 0.05 FTE in stocking room cupboards. Nurses reported more contact time with patients when using room cupboards. Nurses reported fewer interruptions during medication preparation and administration.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Burdeu 2006[124]	Improving safety of intravenous medication administration	Quality improvement project	Plan, do, study, act (PSDA) cycle was used to assess deviations in safe practice of drug infusions, using regular audits by ICU nursing management.	Began with 1 25-bed ICU, then applied lessons learned throughout one acute care teaching hospital in Melbourne, Australia	Provided a medication safety education program and medication calculation worksheets, followed by ongoing PDSA cycles.	Improved drug infusion labeling practices. 90 to 95% of potassium chloride ampoules were removed from the bedside. Preprinted labels were developed for the 5 drug infusions most commonly used. 4-channel infusion pumps were removed from the unit and replaced by double-channel infusion pumps with a simple interface design. Standardized administration of drugs given by bolus dose using a syringe pump. Decreased missed doses of immunosupression drugs for transplant patients from 25% to 9% by incorporating them into the main drug chart. Implemented standardized prefilter and heparin-lock central venous catheters. Eliminated burettes for IV drug infusion. Standardized drug infusion protocols for 36 drugs and provided Intranet-based up-to-date drug information.
Coyle 2005[133]	BCMA	Quality improvement project	Assessed process	161 medical centers in the Veterans Health System	Systemwide change to BCMA and electronic documentation	Acceptance of nurses and “marked decrease” in errors (data for this decrease not described).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Dennison 2007[120]	Medication safety education program	Pre-post test Evaluation study of education program	Technology-enhanced education program	One coronary care unit in one hospital	Two computer-based education modules on medication error reduction and intravenous infusion of high-alert meds.	Nurses knowledge increased from pre- to post-test. Safety climate scores did not change. Labeling of infusion did not change. Number of reported errors did not change.
Fields 2005[130]	Improving safety of intravenous medication administration	Quality improvement project	Rapid-cycle implementation over 6 months, using continuous quality improvement data before and after implementation	100 new systems in 1 hospital in Georgia	Implemented a modular, computerized, integrated infusion system	Most infusion error warnings occurred between 3 p.m. and 9 p.m., and peaked at 6 p.m. 12% of warnings led to changes in pump settings. Risk score associated with heparin infusion rates decreased almost fourfold. Almost all nurses used the new software correctly.
Force 2006[123]	Medication error reporting	Quality improvement project	Used focus groups to gather information on the medication process and process failures to improve error and near-error reporting by pharmacists and nurses	1 hospital in Illinois	Implemented a hospitalwide performance improvement project, emphasizing identifying system factors, not individual blame.	After 1 year of implementation, error reporting increased from a rate of 14.3% to 72.5%.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Franklin 2006[119]	Drug safety education Types of MAEs	Pretest and post-test study	Conducted a drug safety program for nurses and assessed possible improvements in drug safety. Medication administration processes were observed before and after the program.	19 nurses in one hospital ward (63% completed all educational modules).	Web-based drug safety program with 11 modules	The most common types of MAEs were omission, wrong dose, extra dose, and fast intravenous bolus. Rates of nonintravenous MAEs decreased from 6.1% to 4.1%. While nurses used the drug safety program and there was a decrease in nonintravenous MAEs after implementation, there was no significant difference in total MAEs after implementation of the drug safety program.
Franklin 2007[139]	Health technology implementation	Before-and-after study	Reviewed records for prescribing errors, direct observation of nurse med administration	Surgical ward in one hospital in UK	CPOE, BCMA, automated dispensing, electronic medication administration record	MAEs declined from 8.6% to 4.4%. Prescribing errors declined from 3.8% to 2%. Ward pharmacist time increased, prescription time increased, nursing time on medication tasks declined.
Greengold 2003[128]	Medication administration nurses	Randomized controlled trial	Compared using a dedicated nurse for medication administration to nurses administering medications to their patients	2 hospitals	Using a dedicated nurse for medication administration	Generally, there were no significant differences in MAEs between the 2 types of interventions, but MAEs were lower in surgical units and higher in mixed medical and surgical units that used dedicated nurse medication administers.
Larrabee 2003[136]	BCMA	Quality improvement	Descriptive—process and experiences	1 hospital	BCMA	Occurrence reports increased, analysis of systems data for prevented errors found prevalence of “not-due,” wrong-dose, and wrong-patient errors. No omitted and missed doses errors were captured.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Leape 2000[116]	Interventions for reducing adverse drug events	Quality improvement	15-month period of rapid-cycle changes.	36 hospitals participating in an Institute for Healthcare Improvement (IHI) collaborative on reducing adverse drug events.	Education on IHI's method for rapid-cycle change and evaluation	Successful change strategies included nonpunitive reporting; standardized prescribing to reduce illegible handwriting and eliminate leading or trailing zeros; heparin protocols; removal of concentrated potassium chloride from nursing units; improved documentation of allergy information; standardized medication administration time; standardized protocols for chemotherapy; and implementation of insulin-ordering protocols. Of these, removing concentrated potassium chloride from nursing units was 100% successful, and implementing nonpunitive reporting and insulin-ordering protocols were the least successful (50% and 43%, respectively). Success of change strategy was associated with the commitment of the collaborative team (i.e., leadership), effective processes, and appropriate choice of interventions. Failure was attributed to lack of leadership support; ineffective team leadership; unclear aims; poorly designed interventions; lack of focus on underlying system failures; unclear measures; too much focus on data collection; involvement from only some stakeholders; opposition from physicians and nurses; and conflicting time demands for team members.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Mahoney 2007[134]	Integrated clinical information technology	Quality improvement—measures only after implementation	Examined medication errors, turnaround time, decision-support overrides.	Multihospital system	Included CPOE, electronic record, BCMA, decision support, and drug dispensing	System decreased prescribing errors, increased pharmacist interventions, improved monitoring. 73 administration errors for every 100,000 doses were intercepted after implementation.
Meadows 2002[138]	BCMA	Review of BCMA system and effects	Relates briefly the results of two system interventions	2 hospitals	BCMA	The two hospitals had reductions in medication error rates of 71% and 79%. Data used to measure these not described.
Nelson 2005[131]	Decision support to improve medication administration	Pretest and post-test	Collected medication charting data for 8 weeks in both the control and study units. Staff in the study unit received an educational intervention about error avoidance through real-time bedside charting, 12 weeks of monitoring, and performance feedback.	Two 40-bed surgical units in one hospital in Utah	Educational intervention followed up with real-time feedback on documentation.	Medication charting rate increased from 59% to 72% in the intervention group.
Paoletti 2007[140]	BCMA and electronic medication administration record (MAR)	Evaluation study—before and after	Used direct observation to determine MAEs.	3 units in one hospital: 1 control, 2 intervention	BCMA and electronic MAR	Accuracy rate 86.5% before and 97% after.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Paparella 2004[122]	Educational interventions	Quality improvement	Medication safety education, using the NLN Medication Proficiency examination, a medication calculation test, an ongoing continuing educational program on medication safety, and tested medication administration safety simulation models to supplement education.	235-bed community hospital in Pennsylvania	Required medication safety education and calculation testing of all new RNs and LPNs, ongoing medication safety education for current staff, using simulation models "What's Wrong With This Patient."	The educational component for new nurses was used prior to matching with a preceptor during medication administration. The simulation program engaged nursing staff in identifying unsafe medication administration practices.
Papastrat 2003[121]	Educational interventions	Changing practice project	Pilot testing of problem-based learning and systems analysis methods for medication administration to undergraduate nurses.	First-semester baccalaureate nursing students at Thomas Jefferson University	New teaching method	Problem-based learning enabled students to use findings from topic-specific research to develop solutions for clinical problems. Students applied knowledge to clinical settings.
Pape 2003[126]	Reducing distractions during medication administration	Quasi-experiment	Three groups: one control, one used protocol, one used protocol and signage. Outcomes measured by observing medication rounds for distractions.	One medical/surgical unit in one hospital, 24 nurses	Protocol for safe medication administration. Signage—nurse administering medications wore vest asking others not to interrupt.	Distractions were statistically significantly less in the intervention groups, particularly the intervention group using both protocol and signage.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Pape 2005[127]	Reducing distractions during medication administration	Process Improvement	Interventions introduced after observation of distractions. Measured distractions with self-report tool.	5 units in one hospital, 20 nurses	Protocol and checklist for safe medication administration introduced to all nurses. Signage "STOP do not disturb" placed above med prep area.	Self-report of distractions from before and after signage was placed showed decline in distractions from other nurses, other personnel, external conversation, and loud noises.
Rask 2007[117]	Medication safety practices	Cross-sectional study	Survey of hospitals about adoption of National Quality Forum's safe practices and culture of safety	148 hospitals in the United States	None	There was high adoption of standardized labeling and storage of medications (90.5%), identification of high-alert medications (81%), and use of unit doses (81%). For-profit hospitals were more likely than not-for-profit hospitals to have unit-dose medication distribution systems (93.1% vs. 78.2%) and policies on reading back verbal orders (83.1% vs. 58.4%). There were greater distractions affecting medication administration in large hospitals. Hospitals having 100–229 beds were more likely to report using pharmacists to review and approve nonemergency orders prior to dispensing. 69.4% of hospitals use data analysis to drive patient safety quality improvement efforts.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Sakowski 2005[135]	BCMA system	Evaluation study	Effect of implementing BCMA using a retrospective audit of warning and error reports generated by the BCMA system	6 hospitals in a multihospital system.	BCMA	Of 7,120 alerts and warnings, 5,606 actionable warning identified. Users overrode 78%. 25% of items listed as preventable errors and 70% of those labeled as possible errors were noise. Most common types of errors were early doses, wrong dose, doses without order, doses after order discontinued.
Schaubhut2000[132]	Expanding error reporting system Concurrent chart review process	Quality improvement	Reviewed reported medication errors, documentation of medication administration, identified need for medication administration policies, and focus on potential causes of errors	1 hospital in a suburb of New Orleans, LA	A computer-based "unreported meds followup" was created to remind nursing staff about scheduled medications omitted or not documented. Charts were prospectively reviewed, a mandatory medication error prevention seminar was given to nurses, and a medication review report was created for nurses.	Reported error rates increased by 0.5% each year over 3 years. Documentation errors decreased over time.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design & Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Schneider2006[118]	Educational interventions	Randomized controlled trial	Nurses were randomly assigned to use an interactive educational tool on medication administration. Direct observation of medication administration before and after the educational tool.	30 nurses (10 at each site) with at least 1 year experience, working full-time for at least 6 months, at 3 community hospitals in the Midwest within a large nonprofit health system	Interactive medication administration program	Errors in administrative practices decreased at a statistically significant level, errors in preparation increased slightly, and there were too few adverse drug events to analyze.
van Gijssel-Wiersma 2005[141]	Computerized medication charts	Before-after study	Compared prescription errors by review and administration errors by direct observation before and after	1 internal medicine unit	Computerized medication chart, updated daily, compared to handwritten 5-day medication record	Prescribing errors increased, mostly omitted name and date. Administration errors decreased from 10.5% to 6.1%.
Wright 2006[129]	Inpatient self-administration	Literature review	12 studies that measured patient compliance with self-administration programs (SAPs)	Retrieved 455 citations that involved patient SAPs, predominately in hospitals.	None	Even though SAPs varied widely in their structure and content, some SAPs reported that the patients' knowledge of their drug regimen (including the names and dosing frequency of their drugs) improved, but the patients' knowledge of possible side effects of their medications did not increase.

Evidence-Based Practice Implications

Medication safety is a significant issue in hospitals and throughout health care. Great improvements are needed, and hospitals are engaged in many efforts to reduce errors and increase this aspect of patient safety. Unfortunately, there is little evidence on which to base interventions. Based on the research literature, we can have confidence in only two aspects of our knowledge. First, data from voluntary self-reports of medication errors is neither reliable nor valid. Yet, this is the evidence most available for evaluating quality improvement. Interventions to improve the quality of voluntary self-report data include changing the culture to focus on system issues rather than individual deficiencies and having explicit and visible quality management system responses to these data. Staff who do not fear the response to an error report and see that the reports are used to improve quality are much more likely to take the time to report.

The second area about which there is some consensus in the literature is the rate and types of medication administration errors that commonly occur. Using the more reliable and valid data from direct observation studies, we see that the proportion of doses in error is between 20 and 27 percent counting wrong-time errors and between 7 and 18 percent without the wrong-time errors. MAEs are most likely to be wrong time, omissions, and wrong dose (wrong or extra dose). Because the nurse is often the last health care provider in the medication-use process, no one, except the patient, is in a position to intercept those errors. Given the number of medication doses administered each day in U.S. hospitals, the probable number of errors is truly staggering. If hospital patients get 10 doses of medication each day, at least 1 and possibly 3 of those will be wrong.

While the research base for practice interventions is growing, it is still weak for most of the strategies currently recommended to improve medication safety. System-focused strategies include increasing nurse staffing levels, otherwise decreasing workloads, improving the safety climate, and instituting policy and procedures such as RN independent double-checks. There are few research studies describing nurses' perceptions of the impact of these system features and even fewer assessing the actual impact, and none that have implemented and rigorously evaluated the effects of system strategies. Instituting new technological systems is most highly recommended. Given the emphasis, there have been surprisingly few studies actually assessing the impact on error rates of bar-coded medication administration and other medication safety technologies.

Process-focused factors include minimizing distractions and interruptions during medication administration, using equipment correctly, and assessing and monitoring the patients' responses to the medications. Again, a few small, single-site studies have assessed the effects of implementing protocols addressing these issues; but overall, the evidence is weak.

The human factors of knowledge and skills (e.g., mathematical) have been studied for decades, and changes in basic education and nurses' orientation and continuing education have been instituted. Studies linking these strategies to outcomes such as the rate of medication errors have not been completed. The impact of fatigue on MAEs is currently of great interest. But with only one descriptive study available and no interventions tested, it is difficult to know how to approach this issue.

Based on this review of the literature, it is clear that medication errors are an immense problem. When implementing interventions to improve medication safety, use the most reliable

and valid data available, and share the results through publications to make the knowledge available to all.

Research Implications

The implications for research follow directly on the discussion of practice implications. Research in this area is constrained by the need to carry out these projects "in the field." Secondary analysis of existing data sets cannot be used for most of the pertinent questions in this area. Laboratory studies are equally impossible. The situations at the heart of medication safety are complex, multifaceted, and multidisciplinary; knowledge about them must be produced with studies conducted within that complex environment. This requires health care institutions to simultaneously attempt to implement changes that will reduce the problem and evaluate the impact. Essentially, this is quality improvement (QI) work.

The question is, should the results of QI projects be considered evidence and used as part of the knowledge foundation for future evidence-based practice projects?[142] QI is a set of activities intended to improve some aspect of health care processes,[143] a dynamic and changing package of interventions,[144] and identification of ways to implement effective change.[145] For the most part, definitions of QI do not include assessing the effectiveness of these activities or producing knowledge. And yet, reports of QI projects are increasingly used as evidence for practice and organizational change.

Health care institutions are responding to the crisis in quality and safety with frenetic activities designed to bring about improvement. They desperately want evidence that will assist them in knowing which of these activities to focus on. Massive amounts of money are being invested in organizational changes to improve quality and safety with mostly expert advice and hunches to go on. There is little doubt that these projects are well intentioned; many of them suggest changes that are intuitive or reflect common sense. To move beyond the current state of multiple projects targeting similar changes, the industry needs evidence of the effects of specific changes: the direct and indirect effects, the intended and unintended effects, and the cost effectiveness.

By their nature, QI efforts are local, attempt to minimize disruption to the organization, and try to constrain costs of implementation. To justify the organization's investment in the project, there is a desire to show that the project had the intended effect. Further, the directors of the project often want to capitalize on the QI activities by reporting the results publicly, preferably through respected journals or presentations at professional meetings. As a result of these multiple goals, the project usually has only low-cost, superficial evaluation efforts that are then reported as evidence with an emphasis on outcomes supporting the intervention and omission of those that did not. Many current QI studies have significant bias and can cause harm by disseminating results that lead health care institutions to invest in activities that may not improve quality, while ignoring others that could.[146] But, there is no consensus on standards that can be applied to improve this situation. As Mosser and Kane[147] asked recently, What level of proof should we require to conclude that improvement has been achieved? What level of proof is there that the intervention was the cause of improvement?

The problem of bias inherent in local efforts to improve quality is crucial. When organizations make decisions to invest large amounts of money in a QI project, there is understandable reluctance to hear, let alone share, results that show no systematic effects on the outcomes of care. Yet, to produce the science required for future QI efforts, reports of activities

that were ineffective and those that resulted in unintended and disruptive side effects must also be shared with others. Most QI activities cannot be tested with rigorous and controlled research, and we therefore need to develop a QI science to enhance the internal and external validity of the results. We cannot accept poorly conducted studies of efforts to improve quality and safety—it is too crucial to the future of health care. At the same time, we must recognize that the complexity of projects taking place in the real world cannot be simplified and that analytic methods must substitute for experimental controls in this work.[148] Both the practitioners' distrust of research and its accompanying statistics and the researchers' disdain of the messiness of QI activities must be tempered with a better understanding.

Despite concerns about the rigor of QI, it is crucial that these activities be reported to promote learning about implementation methods that worked and those that did not, and the types of projects that produced desired results and those that did not. To maximize learning, these reports must be thorough and include both the intended and unintended outcomes, descriptions of the intervention and implementation must be candid, the robustness of the measures must be clear, and the description of the organizational context must be adequate. Recent guidelines for the publication of QI projects may assist in achieving this thoroughness and transparency.[149] Collaboration between the principals involved in the QI project and health systems researchers would maximize the potential for producing evidence from these field studies. It is unlikely that science will ever develop methods to study implementation and evaluation of QI projects in their natural setting with a level of rigor similar to experiments or clinical trials, and that makes the results of QI projects even more valuable. It is crucial that we learn which QI activities work in which settings and which outcomes can most likely be improved with organizational changes.

The specific issues most in need of research (QI activities) at this time are as follows:

- Bar-coding and other medication safety technology—widely recommended but little or no valid research using before-and-after designs.
- Independent RN double-checks—logical and widely recommended, but no research has been done describing, let alone testing, the effects of this policy.
- Relationship between nurse staffing and medication errors—a few descriptive studies and studies asking RN perceptions of the problem suggest that staffing and workload are major factors, but there are no research studies using valid and reliable data.
- Techniques to reduce distractions, interruptions, other risk factors for medication error need to be tested.
- Methods of effective education in medication safety for nurses and all providers.
- Effectiveness of implementing new checklists, policies, and procedures.
- Understanding work-arounds.
- Methods and techniques for successful implementation of system and process change.

Despite the national emphasis on patient safety and quality care, very little is known about effective medication safety strategies for nurses. The recent IOM report on medication safety [2] identified several areas needing future research, including the following:

- What are the most effective mechanisms to improve communication between patients and clinicians regarding the safe use of medications?
- What are the most effective mechanisms to improve patient education about the safe use of medications?
- Which self-management support strategies are effective in improving patient outcomes?

- How can information about specific medications be effectively used by patients? What is the impact of that information on patients' adherence and communication with clinicians?
- How can patient-centered approaches to medication safety decrease errors associated with medications and improve patient outcomes?
- How can medication-related competencies become a core competency among the current workforce?
- What is the impact of free samples on patient adherence and health outcomes?

Conclusion

There is a large and growing body of research addressing medication safety in health care. This literature covers the extent of the problem of medication errors and adverse drug events, the phases of the medication-use process vulnerable to error, and the threats all of this poses for patients. As this body of literature is evaluated, the fact that there are crucial areas about which we know little becomes apparent. Nurses are most involved at the medication administration phase, although they provide a vital function in detecting and preventing errors that occurred in the prescribing, transcribing, and dispensing stages. Administration errors comprise a significant proportion of all errors and yet, beyond that fact, there isn't much known about the causes or about the effectiveness of proposed solutions. Research addressing the complex process of medication use in hospitals is badly needed and requires a new approach to produce valid knowledge from studies done in the field with few controls of confounding factors.

Search Strategy

A search of the literature was conducted using PubMed® and CINAL®. The key words employed in the search included "adverse drug events," "drug administration," "medication administration," "medication administration errors," "medication error reporting," "medication safety," "nursing," "patient safety," and "work(ing) conditions." This resulted in 1,400 abstracts, which were narrowed as follows. Literature that addressed topics covered in this book on health information technology, specifically computerized provider order entry with clinical decision-support systems (for nurses and/or physicians) and bar-code medication administration systems, children, and medication reconciliation were excluded from this review, as were studies with only physicians and pharmacists as study subjects, those in home health care settings, and those related only to prescribing medications or patient compliance. Additional exclusion criteria included research not differentiating the nursing role in medication administration, administration of medications to reverse adverse drug reactions (e.g., naloxone for opioid overdose), prescribing and dispensing process of medications, and unique specifications regarding specific medications. Reviewed articles were searched for references that we did not already have, and PubMed® links were checked as additional articles were found. The final review also excluded editorials, newsletters, single-case studies, medication safety outside institutional settings (if dealing with patient self-management or adherence), and studies with critically flawed methodology and inadequate reporting. The literature was then also limited to reports written in English and research published in 1997 or later. A total of 70 articles were identified as having met the inclusion criteria as evidence and were discussed in this chapter.

Author Information

Ronda G. Hughes, Ph.D., M.H.S., R.N., senior health scientist administrator, Agency for Healthcare Research and Quality. E-mail: ronda.hughes@ahrq.hhs.gov.

Mary A. Blegen, Ph.D., R.N., F.A.A.N., professor in community health system and director of the Center for Patient Safety, School of Nursing, University of California, San Francisco. E-mail: mary.blegen@nursing.ucsf.edu.

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